COVID-19: The Science We Should Know

Overview

Since the inception of the COVID-19 pandemic in the spring of 2020, the messaging from most governmental authorities and major-media outlets has been largely consistent — COVID-19 poses a grave threat to all of humanity, lockdown policies and mask mandates are necessary to 'stop the spread,' existing diagnostic tests are reliable indicators of infection, no preventatives or treatments exist for COVID-19, the inoculations developed under Operation Warp Speed are 'safe and effective,' and mass inoculation is essential to end the pandemic. Meanwhile, dissenters from this orthodoxy have been routinely vilified and censored, regardless of their qualifications, personal experience, or the substance of their case.

In such a divisive and restrictive environment, acquiring a well-informed understanding of most any COVID-related topic is remarkably challenging. Sensible evaluation of any issue requires familiarity not only with the arguments for prevailing beliefs, but also the evidence presented by knowledgeable skeptics and critics.

This document is intended as a reference resource for anyone curious about the science and data underlying such contrarian positions. Organized by topic, it presents links to primary-source materials, the bulk of which are scientific manuscripts (i.e., scholarly studies, papers, articles, meta-analyses) and related resources. The testimonies of credentialed scientists and medical professionals are also included, while materials based on inexpert opinion have been assiduously avoided.

For ease of use and comprehension, key excerpts accompany most citations, but we strongly encourage you to dig further by following the links and doing your own independent research.

We also want to acknowledge the countless investigators and writers whose efforts have contributed substantially to the content of this document. In particular, we'd like to thank the good people at TheHighwire.com, TheLastAmericanVagabond.com, RationalGround.com, ChildrensHealthDefense.org, AIER.org, Brownstone.org, Mercola.com, TomWoods.com, and TheNHF.com.

To suggest an addition for this compilation meeting the criteria described above, or to notify us in the event that a cited manuscript has been retracted, please send an e-mail to JurorNumber8@protonmail.com.

This compilation is for informational purposes only, and is not predictive or prescriptive. So please think for yourself, do your own due diligence, and draw your own (well-informed) conclusions.

Peace & good health to you and yours.

Updated **April 5, 2023**.

# indicates a cited work to be checked for updates with each release of this document.

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Lockdowns

[1] ***More Than 400 Studies on the Failure of Compulsory Covid Interventions***
Brownstone Institute
Dr. Paul Alexander
November 30, 2021
https://brownstone.org/articles/more-than-400-studies-on-the-failure-of-compulsory-covid-interventions/
Description: Compilation of links to more than 400 studies and other resources with key excerpts from each.

> "The great body of evidence (comparative research studies and high-quality pieces of evidence and reporting judged to be relevant to this analysis) shows that COVID-19 lockdowns, shelter-in-place policies, masks, school closures, and mask mandates have failed in their purpose of curbing transmission or reducing deaths. These restrictive policies were ineffective and devastating failures, causing immense harm especially to the poorer and vulnerable within societies…
>
> What follows is the current totality of the body of evidence (available comparative studies and high-level pieces of evidence, reporting, and discussion) on COVID-19 lockdowns, masks, school closures, and mask mandates. There is no conclusive evidence supporting claims that any of these restrictive measures worked to reduce viral transmission or deaths."

[2] ***Cost of Lockdowns: A Preliminary Report***
American Institute for Economic Research (AIER)
AIER Staff
November 18, 2020
https://www.aier.org/article/cost-of-us-lockdowns-a-preliminary-report/
Description: Compilation of links to and summaries of studies on the consequences of lockdown policies. Categories include Mental Health, Hunger & Poverty, The Economy, Education, Healthcare, and Crime.

> "In the debate over coronavirus policy, there has been far too little focus on the costs of lockdowns. It's very common for the proponents of these interventions to write articles and large studies without even mentioning the downsides.
>
> Here is a brief look at the cost of stringencies in the United States, and around the world, including stay-at-home orders, closings of business and schools, restrictions on gatherings, shutting of arts and sports, restrictions on medical services, and interventions in the freedom of movement."

[3] **ADDED since 2/8/2022**
Disease Mitigation Measures in the Control of Pandemic Influenza
Center for Biosecurity of the University of Pittsburgh Medical Center
Thomas V. Inglesby, Jennifer B. Nuzzo, Tara O'Toole, and D.A. Henderson
September 5, 2006
https://www.aier.org/wp-content/uploads/2020/05/10.1.1.552.1109.pdf
See also *The Vindication of D.A. Henderson*, by Jeffrey Tucker
https://brownstone.org/articles/the-vindication-of-d-h-henderson/

"The threat of an influenza pandemic has alarmed countries around the globe and given rise to an intense interest in disease mitigation measures. This article reviews what is known about the effectiveness and practical feasibility of a range of actions that might be taken in attempts to lessen the number of cases and deaths resulting from an influenza pandemic. The article also discusses potential adverse second- and third-order effects of mitigation actions that decision makers must take into account. Finally, the article summarizes the authors' judgments of the likely effectiveness and likely adverse consequences of the range of disease mitigation measures and suggests priorities and practical actions to be taken…

[T]here has been interest in a range of disease mitigation measures. Possible measures that have been proposed include: isolation of sick people in hospital or at home, use of antiviral medications, hand-washing and respiratory etiquette, large-scale or home quarantine of people believed to have been exposed, travel restrictions, prohibition of social gatherings, school closures, maintaining personal distance, and the use of masks. Thus, we must ask whether any or all of the proposed measures are epidemiologically sound, logistically feasible, and politically viable. It is also critically important to consider possible secondary social and economic impacts of various mitigation measures...

Community Response to a Pandemic: A summary of Possible Actions

… The world has weathered three pandemics during the past century and will certainly surmount the next one. How much damage the pandemic will cause depends to a large extent on the state of readiness of each community and each metropolitan region and the efficacy and reasonableness of its response. The following is a synopsis of the authors' judgments regarding possible disease mitigation measures…

Cancelling or postponing meetings or events involving large numbers of people... [C]cancelling or postponing large meetings would not be likely to have any significant effect on the development of the epidemic. While local concerns may result in the closure of particular events for logical reasons, a policy directing communitywide closure of public events seems inadvisable.

Quarantine. As experience shows, there is **no basis** for recommending quarantine either of groups or individuals. The problems in implementing such measures are formidable, and secondary effects of absenteeism and community disruption as well as possible adverse consequences, such as loss of public trust in government and stigmatization of quarantined people and groups, are likely to be considerable.

Screening passengers at borders or closing air or rail hubs. Experience has shown that these actions are **not effective** and could have serious adverse consequences; thus, they are not recommended.

An overriding principle. Experience has shown that communities faced with epidemics or other adverse events **respond best and with the least anxiety** when the normal social functioning of the community is least disrupted. Strong political and public health leadership to provide reassurance and to ensure that needed medical care services are provided are critical elements. If either is seen to be less than optimal, a manageable epidemic could move toward catastrophe."

Note: The citations below are presented in reverse, chronological order.

[4] **ADDED since 2/8/2022**
Cancer Screening in the United States During the Second Year of the COVID-19 Pandemic
Journal of Clinical Oncology
American Cancer Society
Jessica Star, Preti Bandi, *et al*.
February 23, 2023
https://ascopubs.org/doi/full/10.1200/JCO.22.02170

> "**Purpose**: To examine whether cancer screening prevalence in the United States during 2021 has returned to prepandemic levels using nationally representative data…
>
> **Results**: … Between 2019 and 2021, the number of people who reported receipt of screening in the past year decreased from 28.8 million to 27.7 million (**1.1 million** fewer women in 2021; 95% CI, –2.6 million to 0.5 million) for breast cancer, from 35.9 million to 31.5 million (**4.4 million** fewer women in 2021; 95% CI, –6.3 million to –2.5 million) for cervical cancer, and from 10.3 million to 9.7 million (**0.7 million** fewer men; 95% CI, –1.6 million to 0.2 million) for prostate cancer…
>
> **Discussion**: In this study of population-based nationally representative survey data, past-year screening for breast, cervical, and prostate cancer in the United States decreased anywhere from 6% to 15% between 2019 and 2021, deviating from prepandemic stable or increasing trends…
>
> These declines have significant public health implications as they are expected to lead to more advanced stage cancer diagnosis in the future."

[5] **ADDED since 2/8/2022**
Lockdowns put us at the mercy of disease
The Telegraph
Sunetra Gupta, professor of theoretical epidemiology at University of Oxford
December 9, 2022
https://sci.med.cardiology.narkive.com/PAnd63yT/lockdowns-put-us-at-the-mercy-of-disease

> "It is now widely acknowledged that lockdowns caused harm to our already stretched health service, with many of the direct consequences such as increased cancer and cardiovascular deaths being reported regularly. Most of these harms were entirely predictable. Less obvious was how some of the more indirect consequences of lockdown might play out, such as the effect on our relationship with other pathogens circulating within our communities…
>
> A pathogen entering an immunologically naïve population will start off with a massive 'immunity debt', leading to infections growing very rapidly at this 'epidemic' stage. This is why lockdowns hardly make a dent in the progress of an epidemic, but can have such a significant effect on endemic diseases.
>
> Such effects are, however, transient. Endemic diseases will soon re-establish themselves, and – as we have seen – can return more aggressively than usual on account of the 'immunity debt' they have amassed in the interim.

This can cause all sorts of problems. Naturally, health care systems will have to be prepared for **higher than usual hospitalisations** during this period of re-adjustment…

Disturbing this order can have a profound impact on an individual's ability to resist disease. More than anything, it is clear that we are experiencing an entirely predictable perturbation in our finely balanced ecological relationship with the organisms which are capable of causing serious disease. Eventually that balance will return. The **'immunity debt'** that we have incurred will be gruesomely paid off and scarlet fever will once again become a storybook word."

[6] **ADDED since 2/8/2022**

Increase Seen in Pediatric BMI During Pandemic, Study Finds

American Academy of Pediatrics
October 7, 2022
https://www.aap.org/en/news-room/news-releases/conference-news-releases/increase-seen-in-pediatric-bmi-during-pandemic-study-finds

"A study that tracked body mass index (BMI) two years prior to the pandemic and one year after the start of the pandemic in a primarily Medicaid pediatric population in Norfolk, Virginia, found a significant increase in BMI during that time.

When these differences were analyzed by gender, the increase was only significant for the female cohort, according to the study, 'Examining the Effects of COVID-19 Lifestyle on Pediatric BMI.' There was an **11%** mean increase in the BMI of girls, the study found.

The authors also observed there was a significant correlation between screen time and family time increases during the pandemic and rising pediatric BMIs, as families spent more time at home because of the lockdowns."

[7] **ADDED since 2/8/2022**

COVID-19 and the unseen pandemic of child abuse

BMJ Paediatrics Open
Wesley J. Park and Kristen A. Walsh
September 13, 2022
https://bmjpaedsopen.bmj.com/content/6/1/e001553

"For children, the collateral damage of the COVID-19 pandemic response has been considerable: 'nearly insurmountable' educational losses, deteriorating mental health, low routine childhood vaccination rates, 39 billion missed school meals by January 2021 and millions of estimated life-years lost among students in the USA alone. It is difficult to deny the harmful impact of lockdowns on children, who are society's most vulnerable members. In this paper, we use the framework of evidence-based medicine to argue that child abuse is another negative side effect of COVID-19 lockdowns…

There is emerging evidence that lockdowns significantly worsened child abuse on a global scale. Low-income and middle-income countries are particularly vulnerable to increases in child abuse. In Uganda, for example, there was a 1565% increase in the average number of calls per day to the Uganda Child Helpline in the first month of lockdown. Yet, even wealthy nations in the West did not escape unscathed. In the UK, there was a 1493% increase in cases of abusive head trauma at Great Ormond Street Hospital. In France, there was an 89% increase in national child abuse helpline calls, a 48% increase in home visits by law

enforcement officers and a 50% increase in the relative frequency of child abuse hospitalisations. Furthermore, there appears to have been insidious changes with potentially long-term effects which are more difficult to measure. In the Netherlands, for example, there was a 32% increase in previously rare harsh parenting behaviours, including shaking and name calling…

We conclude that lockdowns have an unacceptably high risk of negative side effects for children, as evidenced by child abuse, the true extent of which appears to be masked by lockdown-related disruptions to schools and other surveillance systems. Rather than a 'missing epidemic', perhaps a more appropriate name for lockdown-related child abuse is an unseen pandemic—hidden in plain sight."

[8] **ADDED since 2/8/2022**

'The results confirm our fears': Federal school test scores dropped during pandemic

Politico
Juan Perez Jr.
September 1, 2022
https://www.politico.com/news/2022/09/01/federal-school-test-scores-dropped-pandemic-00054414

"Test scores for the country's 9-year-olds suffered significant declines early this year when compared to early 2020, according to federal data released Thursday that will reinforce the worries of educators and politicians over Covid-19's impact on children.

Students who took National Assessment of Educational Progress long-term trend tests this past winter scored an average of seven points lower in math and five points lower in reading when compared to 9-year-olds who took the same federal exam in 2020 — just before the pandemic was declared a global health emergency and physical classrooms shuttered.

Those results mean notably fewer students could carry out simple reading tasks or understand texts, or handle arithmetic and early math problem solving…

The overall reading score decline marked the test's **largest drop of statistical significance since the 1980s**, while the drop in math scores marked the **first such drop ever recorded** since the government first tested learning trends on the subject during the 1970s."

[9] **ADDED since 2/8/2022**

Exercise Rates Still Haven't Recovered From Pandemic, Global Study Shows

US News & World Report
Cara Murez
September 1, 2022
https://www.usnews.com/news/health-news/articles/2022-09-01/exercise-rates-still-havent-recovered-from-pandemic-global-study-shows

"Researchers from the University of California, San Francisco examined worldwide trends in physical activity by measuring step counts in the two years following the start of the pandemic. Step counts were distinctly lower early in the pandemic compared to pre-pandemic levels and remained lower for the first two years of the global crisis, the study team found…

The research team found a rate of 5,323 steps a day during the 2019 calendar year. The average step count from November 2021 to February 2022 was lower for all continents

compared with the same 90-day time period in 2019-2020. That same November to February time period for 2020-2021 was also lower for all continents compared with the pre-pandemic period.

The best recovery period of gaining step counts worldwide was in May to November 2021, with 4,997 steps a day, but this was still 10% lower than the same time frame in 2019. Step counts recovered the most in North America, where they remained 4% lower, and Europe, where they remained 14% lower. They recovered the least in South America and Asia."

[10] **ADDED since 2/8/2022**

Lockdown effects feared to be killing more people than Covid — Unexplained excess deaths outstrip those from virus as medics call figures 'terrifying'

The Telegraph
Sarah Knapton, Science Editor
August 18, 2022
https://archive.ph/xK9wL#selection-1337.1-1337.61

"The effects of lockdown may now be killing more people than are dying of Covid, official statistics suggest.

Figures for excess deaths from the Office for National Statistics (ONS) show that around 1,000 more people than usual are currently dying each week from conditions other than the virus...

Dr Charles Levinson, the chief executive of Doctorcall, a private GP service, said his company was seeing 'far too many' cases of undetected cancers and cardiac problems, as well as 'disturbing' numbers of mental health conditions.

'Hundreds and hundreds of people dying every week – what is going on?' he said. 'Delays in seeking and receiving healthcare are no doubt the driving force, in my view…'

Figures released by the ONS on Tuesday showed that **excess deaths are currently 14.4 per cent higher than the five-year average**, equating to 1,350 more deaths than usual in the week ending Aug 5…

Questioned by The Telegraph, the Department of Health admitted it had asked the Office for Health Improvement and Disparities to look into the figures and had discovered that the majority were linked to **largely preventable heart and stroke and diabetes-related conditions**.

Many appointments and treatments were cancelled as the NHS battled the pandemic throughout 2020 and last year, leading to a huge backlog that the health service is still struggling to bring down...

Last week, official England-wide statistics showed emergency care standards had hit an all-time low."

[11] **ADDED since 2/8/2022**

Limitations of models for guiding policy in the COVID-19 pandemic

University of Edinburgh
Paul M. McKeigue and Simon N. Wood
June 30, 2022
https://www.medrxiv.org/content/10.1101/2022.06.30.22277091v1.full-text

"**Abstract**: At the outset of the COVID-19 epidemic in the UK, infectious disease modellers advised the government that unless a lockdown was imposed, most of the population would be infected within a few months and critical care capacity would be overwhelmed. This paper investigates the quantitative arguments underlying these predictions, and draws lessons for future policy…

Discussion: The analyses above show that of the four propositions on which the recommendation for lockdown was based, one – the assumption that 2% of those infected would require critical care – was unequivocally wrong, and another – that mitigation through focused protection would not be effective in limiting morbidity and mortality – was not seriously questioned. The other two propositions – that in an unmitigated epidemic 80% would be infected, and that only a lockdown could suppress the epidemic – were reliant on strong but unrealistic modelling assumptions and weak data…

The modelling reports at the outset of the epidemic in March 2020 failed to communicate that by relying on the unrealistic assumption of no unmeasured heterogeneity they were likely to overestimate the size of the epidemic, and that no reliable prediction of the effects of non-pharmaceutical interventions could be made without more information about the mode of transmission. This suggests that policy advice in future epidemics should rely less on models, with a greater priority given to the rapid establishment of high quality direct measurement studies."

[12] **ADDED since 2/8/2022**

No learning loss in Sweden during the pandemic: Evidence from primary school reading assessments

International Journal of Educational Research
Anna Eva Hallin, Henrik Danielsson, ThomasNordström, and Linda Fälth
June 2, 2022
https://www.sciencedirect.com/science/article/pii/S0883035522000891

"**Abstract**: The COVID-19 pandemic has led to worldwide school closures, with a risk of learning loss. Sweden kept primary schools open, but it is unknown whether student and teacher absence and pandemic-related stress factors affected teaching and student progress negatively. In this study, reading assessment data from 97,073 Swedish primary school students (grades 1-3) were analysed to investigate potential learning loss. Results showed that word decoding and reading comprehension scores were not lower during the pandemic compared to before the pandemic, that students from low socio-economic backgrounds were not especially affected, and that the proportion of students with weak decoding skills did not increase during the pandemic. Study limitations are discussed. We conclude that open schools benefitted Swedish primary school students.

1. Introduction: School closures affected over 90% of the world's students early in the pandemic (UNESCO, 2020), and one year later almost half of the world's students were still affected by partial or full school closures…

Early models of effects on school closures during the pandemic (for the 2019-2020 school year) showed rather grim projections (Azevedo et al., 2020; Bao et al., 2020; Kuhfeld et al., 2020). Kuhfeld et al. (2020)…

A few studies have confirmed that school closures did have a particularly negative effect on disadvantaged students (Engzell, Frey, & Verhagen, 2021; Maldonado & De Witte, 2021), low-achieving students (Clark et al., 2021), and younger students (Tomasik et al., 2021)."

[13] **ADDED since 2/8/2022**

The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good

BMJ Global Health
Kevin Bardosh, Alex de Figueiredo, *et al.*
May 26, 2022
https://gh.bmj.com/content/7/5/e008684

"**Abstract**: Vaccination policies have shifted dramatically during COVID-19 with the rapid emergence of population-wide vaccine mandates, domestic vaccine passports and differential restrictions based on vaccination status. While these policies have prompted ethical, scientific, practical, legal and political debate, there has been limited evaluation of their potential unintended consequences. Here, we outline a comprehensive set of hypotheses for why **these policies may ultimately be counterproductive and harmful**. Our framework considers four domains: (1) behavioural psychology, (2) politics and law, (3) socioeconomics, and (4) the integrity of science and public health. While current vaccines appear to have had a significant impact on decreasing COVID-19-related morbidity and mortality burdens, we argue that current mandatory vaccine policies are scientifically questionable and are likely to cause more societal harm than good. Restricting people's access to work, education, public transport and social life based on COVID-19 vaccination status impinges on human rights, promotes stigma and social polarisation, and adversely affects health and well-being. Current policies may lead to a widening of health and economic inequalities, detrimental long-term impacts on trust in government and scientific institutions, and reduce the uptake of future public health measures, including COVID-19 vaccines as well as routine immunisations. Mandating vaccination is one of the most powerful interventions in public health and should be used sparingly and carefully to uphold ethical norms and trust in institutions. We argue that current COVID-19 vaccine policies should be re-evaluated in light of the negative consequences that we outline. Leveraging empowering strategies based on trust and public consultation, and improving healthcare services and infrastructure, represent a more sustainable approach to optimising COVID-19 vaccination programmes and, more broadly, the health and well-being of the public.

Summary box:

- Mandatory COVID-19 vaccine policies have been used around the world during the COVID-19 pandemic to increase vaccination rates. But these policies have provoked considerable social and political resistance, suggesting that they have unintended harmful consequences and may not be ethical, scientifically justified, and effective.

- We outline a comprehensive set of hypotheses for why current COVID-19 vaccine policies may prove to be both counterproductive and damaging to public health. Our framework synthesizes insights from behavioural psychology (reactance, cognitive dissonance, stigma, and distrust), politics and law (effects on civil liberties, polarization, and global governance), socio-economics (effects on inequality, health system capacity and social wellbeing) and the integrity of science and public health (the erosion of public health ethics and regulatory oversight).

- Our analysis strongly suggests that **mandatory COVID-19 vaccine policies have had damaging effects on public trust, vaccine confidence, political polarization, human rights, inequities and social wellbeing**. We question the effectiveness and consequences of coercive vaccination policy in pandemic response and urge the public health community and policymakers to return to non-discriminatory, trust-based public health approaches."

[14] **ADDED since 2/8/2022**

Tens of Thousands of Boys in Bangladesh Were Forced into Work During the Pandemic. Now School Is Resuming Without Them

Time magazine
Corinne Redfern and Ali Ahsan
April 26, 2022
https://time.com/6170432/bangladesh-child-labor-pandemic/

> "When authorities first shuttered Bangladesh's schools in March 2020, nobody could have anticipated they would remain closed for the following 18 months, in what would go on to become one of the most restrictive school closures in the world… Now, two years on from the first lockdown, child-rights advocates say that tens of thousands of pupils across the country have not returned to school. The majority, they say, are boys ages 12 and above, who during the interim were pushed into full-time work…
>
> [A]s household incomes across the country plunged by an average of 23% during the first 18 months of the pandemic, many parents say they're out of alternatives: unless their son goes to work, his siblings won't be able to eat…
>
> When the pandemic first hit, concern initially focused on girls being forced into marriage, as struggling families tried to reduce their costs by marrying off their daughters to men sometimes more than twice their age. One survey conducted by the nonprofit Manusher Jonno Foundation recorded almost **14,000 underage marriages** across one-third of the country during the first six months of lockdown, with half of the girls ages 13 to 15."

[15] **ADDED since 2/8/2022**

Many U.S. teens report emotional and physical abuse by parents during the pandemic.

New York Times
Ellen Barry
March 31, 2022
https://www.nytimes.com/2022/03/31/world/americas/many-us-teens-report-emotional-and-physical-abuse-by-parents-during-the-pandemic.html

"A nationwide survey of 7,705 high school students conducted in the first half of 2021 built on earlier findings of high levels of emotional distress, with **44.2 percent** describing persistent feelings of sadness or hopelessness that prevented them from participating in normal activities, and **9 percent** reporting an attempt at suicide.

It also found high rates of reported abuse, with 55.1 percent of teenage respondents saying they suffered emotional abuse from a parent or another adult in their house in the preceding year, and **11.3 percent** saying they suffered physical abuse.

In the survey, emotional abuse was defined as swearing, insulting or belittling; physical abuse was defined as hitting, beating, kicking or physically hurting.

Research conducted before the pandemic, in 2013, showed that self-reports of parental abuse were substantially lower, with 13.9 percent of respondents ages 14 to 17 reporting emotional abuse during the preceding year, and 5.5 percent reporting physical abuse."

[16] **ADDED since 2/8/2022**

Children Under Five Dying from Economic 'Side Effects' of COVID-19 Pandemic
Johns Hopkins Center for Communication Programs
Stephanie Desmon
February 23, 2022
https://ccp.jhu.edu/2022/02/23/child-mortality-lockdowns-pandemic-covid19/
Source study: ***Estimated impact of the 2020 economic downturn on under-5 mortality for 129 countries***
PLOS One — Johns Hopkins Bloomberg School of Public Health
Marcelo Cardona, Joseph Milward, Alison Gemmill, Katelyn Jison Yoo, and David M. Bishai
February 23, 2022
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0263245

"Economic downturns in 129 of the world's low- and middle-income countries due to COVID-19-related lockdowns, border closings and more may have killed hundreds of thousands of children under the age of five in the first year of the pandemic.

The findings, published today in the journal PLOS One, shine light on a hidden COVID-19 death toll – young children who die not from the disease, but from the disruptions in food and medicine deliveries, closed health clinics and delays in childhood immunizations that have resulted from precautions taken to reduce the spread of the virus. Nearly **half of the excess deaths of children** are estimated to have **occurred in sub-Saharan Africa**…

The model created by the researchers looked at additional deaths in 2020 to be expected in children under 5 with a range of recession rates: a 5 percent, 10 percent and 15 percent reduction in a country's gross domestic product (GDP). **In the most conservative case**, a GDP per capita reduction of 5 percent, **the researchers estimated that between 279,000 and 286,000 additional lives of children under 5 were lost** due to indirect effects of COVID-related recessions in 2020. That translates to an additional 43,000 deaths in India and an extra 22,000 deaths in Nigeria compared to an average year.

At 10 percent and 15 percent, recessions would lead to higher losses of lives in children under 5, increasing to 585,802 and 911,026 additional deaths, respectively…

The International Monetary Fund estimates that the global economy shrank by 4.4 percent in 2020 compared with a contraction of just 0.1 percent in 2009, during the financial crisis known as the Great Recession. The economic downturns of 2020 are projected to reverse a sustained trend of decline in global poverty, with **an expected 42 to 66 million additional children falling into extreme poverty** as a result."

[17] ***A Literature Review and Meta-Analysis of the Effects of Lockdowns on COVID-19 Mortality***
Johns Hopkins Institute for Applied Economics, Global Health, and the Study of Business Enterprise
Jonas Herby, Lars Jonung, and Steve H. Hanke
January 2022
https://sites.krieger.jhu.edu/iae/files/2022/01/A-Literature-Review-and-Meta-Analysis-of-the-Effects-of-Lockdowns-on-COVID-19-Mortality.pdf

"**Abstract**: This systematic review and meta-analysis are designed to determine whether there is empirical evidence to support the belief that 'lockdowns' reduce COVID-19 mortality. Lockdowns are defined as the imposition of at least one compulsory, non-pharmaceutical intervention (NPI). NPIs are any government mandate that directly restrict peoples' possibilities, such as policies that limit internal movement, close schools and businesses, and ban international travel. This study employed a systematic search and screening procedure in which 18,590 studies are identified that could potentially address the belief posed. After three levels of screening, 34 studies ultimately qualified. Of those 34 eligible studies, 24 qualified for inclusion in the meta-analysis. They were separated into three groups: lockdown stringency index studies, shelter-in-placeorder (SIPO) studies, and specific NPI studies. An analysis of each of these three groups support the conclusion that lockdowns have had little to no effect on COVID-19 mortality. More specifically, stringency index studies find that **lockdowns in Europe and the United States only reduced COVID-19 mortality by 0.2% on average** [*emphasis added*]. SIPOs were also ineffective, only reducing COVID-19 mortality by 2.9% on average. Specific NPI studies also find no broad-based evidence of noticeable effects on COVID-19 mortality.

While this meta-analysis concludes that lockdowns have had little to no public health effects, they have imposed enormous economic and social costs where they have been adopted. In consequence, **lockdown policies are ill-founded and should be rejected as a pandemic policy instrument** [*emphasis added*]…

Policy implications: … The use of lockdowns is a unique feature of the COVID-19 pandemic. Lockdowns have not been used to such a large extent during any of the pandemics of the past century. However, lockdowns during the initial phase of the COVID-19 pandemic have had **devastating effects**. They have contributed to reducing economic activity, raising unemployment, reducing schooling, causing political unrest, contributing to domestic violence, and undermining liberal democracy. These costs to society must be compared to the benefits of lockdowns, which our meta-analysis has shown are marginal at best. Such a standard benefit-cost calculation leads to a strong conclusion: **lockdowns should be rejected out of hand** as a pandemic policy instrument [*emphasis added*]."

[18] ***Ministry of Health, it's time to admit failure***
N12 News (Israel)
Ehud Qimron, head of the Department of Microbiology and Immunology at Tel Aviv University
January 6, 2022
https://www.mako.co.il/news-columns/2022_q1/Article-dfd99ca599e2e71026.htm

> "Two years late, you finally realize that a respiratory virus cannot be defeated and that any such attempt is doomed to fail. You do not admit it, because you have admitted almost no mistake in the last two years, but in retrospect it is clear that you have failed miserably in almost all of your actions, and even the media is already having a hard time covering your shame…
>
> [F]rom the heights of your hubris, you have also ignored the fact that in the end the truth will be revealed. And it begins to be revealed. The truth is that you have brought the public's trust in you to an unprecedented low, and you have eroded your status as a source of authority. The truth is that you have burned hundreds of billions of shekels to no avail – for publishing intimidation, for ineffective tests, for destructive lockdowns and for disrupting the routine of life in the last two years…
>
> You slandered colleagues who did not surrender to you, you turned the people against each other, divided society and polarized the discourse. You branded, without any scientific basis, people who chose not to get vaccinated as enemies of the public and as spreaders of disease. You promote, in an unprecedented way, a draconian policy of discrimination, denial of rights and selection of people, including children, for their medical choice. A selection that lacks any epidemiological justification."

[19] ***Protecting Youth Mental Health: The U.S. Surgeon General's Advisory***
US Surgeon General
December 2021
https://www.hhs.gov/sites/default/files/surgeon-general-youth-mental-health-advisory.pdf

> "Since the pandemic began, rates of psychological distress among young people, including symptoms of anxiety, depression, and other mental health disorders, have increased. Recent research covering 80,000 youth globally found that **depressive and anxiety symptoms doubled** during the pandemic, with 25% of youth experiencing depressive symptoms and 20% experiencing anxiety symptoms. Negative emotions or behaviors such as impulsivity and irritability—associated with conditions such as ADHD—appear to have moderately increased. Early clinical data are also concerning: In early 2021, emergency department visits in the United States for suspected suicide attempts were **51% higher** for adolescent girls [*emphasis added*] and 4% higher for adolescent boys compared to the same time period in early 2019.45 Moreover, pandemic-related measures reduced in-person interactions among children, friends, social supports, and professionals such as teachers, school counselors, pediatricians, and child welfare workers. This made it harder to recognize signs of child abuse, mental health concerns, and other challenges."

[20] ***Health costs pushed or worsened poverty for over 500 mln***
Reuters
Manas Mishra
December 13, 2021
https://www.reuters.com/business/healthcare-pharmaceuticals/health-costs-during-pandemic-pushed-over-half-billion-people-into-poverty-2021-12-12/

> "More than half a billion people globally were pushed or sent further into extreme poverty last year as they paid for health costs out of their own pockets, with the COVID-19 pandemic expected to make things worse, the World Health Organization and the World Bank said on Sunday.
>
> The pandemic disrupted health services globally and triggered the worst economic crisis since the 1930s, making it even more difficult for people to pay for healthcare, according to a joint statement from both the organizations."

[21] **ADDED since 2/8/2022**
The State of the Global Education Crisis: A Path to Recovery
A joint UNESCO, UNICEF, and World Bank report
December 3, 2021
https://documents1.worldbank.org/curated/en/416991638768297704/pdf/The-State-of-the-Global-Education-Crisis-A-Path-to-Recovery.pdf

> "**Executive Summary**: The global disruption to education caused by the COVID-19 pandemic is without parallel, and its effects on learning have been severe. The crisis brought education systems across the world to a halt, with school closures affecting more than 1.6 billion learners. While nearly every country in the world offered remote learning opportunities for students, the quality and reach of such initiatives varied greatly, and they were at best partial substitutes for in-person learning. Now, 21 months later, schools remain closed for millions of children and youth, and millions more are at risk of never returning to education. Growing evidence on the impacts of school closures on children's learning depicts a harrowing reality. Learning losses have been large and inequitable: recent learning assessments show that children in many countries have missed out on most or all of the academic learning they would ordinarily have acquired in school, with younger and more marginalized children often missing out the most. Students in São Paulo (Brazil) learned only 28 percent of what they would have in face-to-face classes and the risk of dropout increased more than threefold. In rural Karnataka (India), the share of grade three students in government schools able to perform simple subtraction fell from 24 percent in 2018 to only 16 percent in 2020. The global learning crisis has grown by even more than previously feared: **this generation of students now risks losing $17 trillion in lifetime earnings in present value as a result of school closures**, or the equivalent of 14 percent of today's global GDP, far more than the $10 trillion estimated in 2020. In low- and middle-income countries, **the share of children living in Learning Poverty**—already over 50 percent before the pandemic—**will rise sharply, potentially up to 70 percent**, given the long school closures and the varying quality and effectiveness of remote learning."

[22] ***Covid horror as 'staggering' backlog of missed cancer diagnoses could hit 50,000***
UK Express
Michael Curzon
November 26, 2021
https://www.express.co.uk/news/uk/1527600/covid-news-NHS-cancer-backlog-missed-diagnoses

> "Macmillan Cancer Support has estimated that more than 47,000 people in the UK have missed a cancer diagnosis since the first lockdown.
>
> Amid warnings of new Covid variants and further disruption to the NHS this winter, the charity added that the number of missed diagnoses could increase further still.
>
> Steven McIntosh, Executive Director of Advocacy and Communications at the charity, said: 'Nearly two years into the pandemic, there is still a mountain of almost 50,000 people who are missing a cancer diagnosis.'"

[23] ***Unexplained surge in non-Covid deaths triggers calls for probe***
The Week (UK)
Julia O'Driscoll
November 17, 2021
https://www.theweek.co.uk/news/science-health/954825/extra-non-covid-deaths-increase

> "Almost 9,300 more people [*in the UK*] than usual have died from conditions unrelated to coronavirus since July…
>
> Experts are demanding an urgent inquiry into whether thousands of non-Covid deaths since July could have been prevented…
>
> Kevin McConway, emeritus professor of applied statistics at The Open University, said that the recent surge in excess deaths included 'considerable excess numbers of deaths in people's own homes, compared to the 2015-19 average'…
>
> Sarah Caul, head of mortality analysis at the non-ministerial department, said that the pandemic 'appears to have had an indirect effect' on rates of deaths outside of healthcare settings.
>
> 'This could be because of a combination of factors which may include health service disruption, people choosing to stay away from healthcare settings or terminally ill people staying at home rather than being admitted to other settings for end-of-life care,' Caul added."

[24] ***NHS waiting lists: Backlog hits record high with nearly six million awaiting treatment in England***
Sky News (UK)
Lucia Binding
October 14, 2021
https://news.sky.com/story/nhs-waiting-lists-backlog-hits-record-high-with-nearly-six-million-awaiting-treatment-in-england-12433516

> "Figures from NHS England showed that 5.7 million people were on waiting lists at the end of August, which is the highest figure since records began in August 2007.

Of those, some 9,754 people had been waiting more than two years to begin hospital treatment, more than three times the 2,722 people who were waiting longer than two years in April."

[25] ***The Long-Term Impact of the COVID-19 Unemployment Shock on Life Expectancy and Mortality Rates***
National Bureau of Economic Research (NBER)
Francesco Bianchi (Duke University), Giada Bianchi (Harvard Medical School), and Dongho Song (Johns Hopkins University)
Revised September 2021
https://www.nber.org/system/files/working_papers/w28304/w28304.pdf

"**Abstract**: … We use our results to assess the long-run effects of the COVID-19 economic recession on mortality and life expectancy. We estimate the size of the COVID-19-related unemployment shock to be between **2 and 5 times larger than the typical unemployment shock**, depending on race and gender, resulting in a significant increase in mortality rates and drop in life expectancy. We also predict that the shock will disproportionately affect African-Americans and women, over a short horizon, while the effects for white men will unfold over longer horizons. These figures translate in more than **0.8 million additional deaths** over the next 15 years [*emphasis added*].

4.1 Effects on life expectancy and death rates…

Table 6 reports the cumulative effect of the COVID-19 unemployment shock on life expectancy and death rates as predicted by our model at different horizons. The first row in each panel of Table 6 reports the results for the overall population. At the 15-year horizon, the death rate is 2.43% higher and life expectancy is 0.83% lower. These numbers represent the marginal effect of the shock: they indicate the expected change in life expectancy and death rates following the COVID-19 unemployment shock keeping fixed other factors that affect these measures of well-being, like the progress in health care.

Table 6: Cumulative changes of life expectancy and age-adjusted death rates over different horizons following the COVID-19 unemployment shock

	(1) Percentage change in life expectancy			
	5 years	10 years	15 years	20 years
Overall population	−0.42 [−0.95,0.01]	−0.80 [−1.97,0.00]	−0.83 [−2.27,0.00]	−0.83 [−2.29,0.00]
African-American	−0.58 [−1.13,−0.16]	−1.20 [−2.64,−0.32]	−1.16 [−3.16,−0.25]	−1.09 [−3.17,−0.28]
African-American (M)	−0.84 [−1.46,−0.33]	−1.57 [−3.06,−0.58]	−1.53 [−3.64,−0.52]	−1.47 [−3.70,−0.54]
African-American (W)	−0.62 [−1.21,−0.14]	−1.34 [−2.97,−0.27]	−1.32 [−3.65,−0.16]	−1.21 [−3.66,−0.15]
White	−0.37 [−0.94,0.10]	−0.72 [−2.01,0.15]	−0.75 [−2.34,0.16]	−0.76 [−2.41,0.17]
White (M)	−0.40 [−0.93,0.07]	−0.85 [−2.14,0.09]	−0.94 [−2.66,0.11]	−0.94 [−2.85,0.12]
White (W)	−0.52 [−1.28,0.16]	−0.99 [−2.74,0.28]	−1.01 [−3.16,0.34]	−1.00 [−3.15,0.35]
	(2) Percentage change in the age-adjusted death rate			
	5 years	10 years	15 years	20 years
Overall population	1.83 [0.41,3.55]	2.56 [0.61,5.67]	2.43 [0.57,5.70]	2.42 [0.56,5.52]
African-American	2.90 [1.34,4.81]	4.38 [1.81,8.88]	3.70 [1.34,9.22]	3.56 [1.41,8.76]
African-American (M)	2.72 [1.00,4.83]	4.33 [1.44,9.15]	3.92 [1.03,9.92]	3.84 [1.00,9.95]
African-American (W)	3.46 [1.67,5.70]	5.95 [2.68,11.86]	5.21 [1.98,12.55]	4.71 [1.86,11.71]
White	2.16 [0.62,4.14]	3.09 [0.89,6.97]	2.91 [0.87,7.02]	2.93 [0.87,6.82]
White (M)	1.71 [0.14,3.54]	3.04 [0.34,7.20]	3.16 [0.37,8.47]	3.14 [0.33,8.72]
White (W)	3.19 [0.80,5.98]	4.78 [1.30,10.73]	4.41 [1.25,11.04]	4.40 [1.27,10.41]

Notes: The table shows the predicted cumulative percentage change in life expectancy and age adjusted mortality rate at 5, 10, 15 and 20 years. We present the median values and provide the values that correspond to the 90% bands in brackets. Results are presented for the overall US population and subdivided based on race and gender.

Table 9 provides the respective numbers for the overall population and the different groups identified based on race and gender. For the overall population, the increase in the death rate following the COVID-19 pandemic implies a staggering **0.84 and 1.22 million excess deaths** over the next 15 and 20 years, respectively [*emphasis added*]…

[I]t is important to emphasize that our results are in line with studies that take a completely different methodological approach and focus on specific cohorts or individuals. For example, Schwandt and von Wachter (2020) argue that cohorts coming of age during a deep recession suffer increases in mortality later in their middle age. von Wachter (2020) focuses on the effects of the COVID-19 recession for mortality rates of vulnerable job losers and labor market entrants and also finds that the losses in potential life years due to unemployment could be substantially larger than those from deaths directly due to COVID-19. With respect to these studies, our time-series approach allows for the possibility that the state of the economy, as captured by the unemployment rate, might affect the general population through indirect channels such as income, poverty rates, crime rates."

[26] ***Longitudinal Trends in Body Mass Index Before and During the COVID-19 Pandemic Among Persons Aged 2–19 Years — United States, 2018–2020***
CDC
Samantha J. Lange, Lyudmyla Kompaniyets, *et al*.
September 17, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7037a3-H.pdf

> "Obesity is a serious health concern in the United States, affecting more than one in six children and putting their long-term health and quality of life at risk. During the COVID-19 pandemic, children and adolescents spent more time than usual away from structured school settings, and families who were already disproportionally affected by obesity risk factors might have had additional disruptions in income, food, and other social determinants of health. As a result, children and adolescents might have experienced circumstances that accelerated weight gain, including increased stress, irregular mealtimes, less access to nutritious foods, increased screen time, and fewer opportunities for physical activity (e.g., no recreational sports)… **Between the prepandemic and pandemic periods, the rate of BMI increase approximately doubled**, from 0.052 (95% confidence interval [CI] = 0.051–0.052 to 0.100 (95% CI = 0.098–0.101) [*emphasis added*]."

[27] ***Dr. Scott Atlas: Science Killed Itself Over COVID-19***
Helen Raleigh
September 1, 2021
https://thefederalist.com/2021/09/01/dr-scott-atlas-science-killed-itself-over-covid-19/

> "Lockdowns destroyed people, Atlas said, by 'shutting down medical care, stopping people from seeking emergency medical care, increasing drug abuse, increasing death by suicide, more psychological damage, particularly among the younger generation. Hundreds and thousands of child abuse cases went unreported. Teenagers' self-harm cases have tripled.'
>
> Atlas also noted the increase of other deaths like tuberculosis, caused by the world's focus on COVID-19. The World Health Organization warned in 2020 of up to an additional 400,000 deaths from tuberculosis because of the diversion of resources to COVID-19. 'Mortality data showing that anywhere from a third or half of the deaths during the pandemic were not due to COVID-19,' Atlas said. '**They were extra deaths due to the lockdowns** [*emphasis added*].'"

[28] ***Impact of the COVID-19 Pandemic on Early Child Cognitive Development: Initial Findings in a Longitudinal Observational Study of Child Health***
Brown University and the RESONANCE Consortium
Sean CL Deoni, Jennifer Beauchemin, Alexandra Volpe, Viren D'Sa, and the RESONANCE Consortium
August 11, 2021
https://www.medrxiv.org/content/10.1101/2021.08.10.21261846v1.full-text

> "**Abstract**: Since the first reports of novel coronavirus in the 2020, public health organizations have advocated preventative policies to limit virus, including stay-at-home orders that closed businesses, daycares, schools, playgrounds, and limited child learning and typical activities. Fear of infection and possible employment loss has placed stress on parents; while parents who could work from home faced challenges in both working and providing full-time attentive childcare. For pregnant individuals, fear of attending prenatal visits also increased maternal stress, anxiety, and depression. Not surprising, there has been concern over how these

factors, as well as missed educational opportunities and reduced interaction, stimulation, and creative play with other children might impact child neurodevelopment. Leveraging a large on-going longitudinal study of child neurodevelopment, we examined general childhood cognitive scores in 2020 and 2021 vs. the preceding decade, 2011-2019. We find that children born during the pandemic have **significantly reduced verbal, motor, and overall cognitive performance** compared to children born pre-pandemic [*emphasis added*]. Moreover, we find that males and children in lower socioeconomic families have been most affected. Results highlight that even in the absence of direct SARS-CoV-2 infection and COVID-19 illness, the environmental changes associated COVID-19 pandemic is significantly and negatively affecting infant and child development…

Results: … Across all measures, we found cognitive scores were significantly reduced during the pandemic by 27 to 37 points (or almost two full standard deviations)…

Discussion: Children are inherently shaped by their environment. Across the fetal, infant, and early childhood lifestages, a child's brain undergoes immense structural and functional growth that is driven by an integrative mixture of genetic and environmental factors. The outbreak of the COVID-19 pandemic, and the associated economic shut-down, school disruptions, and social distancing, stay-at-home, and mask policies have fundamentally altered the environment in which children and pregnant individuals have lived, over the past 18 months…

Leveraging data collected continuously over the past decade in Providence, RI and surrounding areas, we sought to investigate how the pandemic has impacted cognitive development and function in newborns and young children. Included pregnant individuals and children reported no symptoms of SARS-CoV-2 infection or had evidence of positive antibody or RT-PCR testing. Families also reported having adhered to stay-at-home and on-going mask and social distancing policies, suggesting **observed effects are environmentally driven rather than due to potential direct effects of infection** [*emphasis added*]…

[Y]oung infants born since the beginning of the pandemic show significantly lower performance than infants born before January 2019. Thus, our results seem to suggest that early development is impaired by the environmental conditions brought on by the pandemic."

[29] **ADDED since 2/8/2022**

Duke Health warns of sharp increase in suicide attempts among children, young adults

WRAL News
Rick Armstrong
July 13, 2021
https://www.wral.com/duke-webinar-offers-psychiatric-panel-discussion-about-a-growing-child-and-adolescent-mental-health-crisis/20373404/

"Pandemic fueled anxiety, self harm and suicide are now increasing among American children and teens. The American Academy of Pediatrics has declared it a national emergency…

The experts said since 2019, the risk of suicide among youth has grown dramatically.

There's been a '15-fold increase of children and young adults coming to our hospital because of such serious suicide attempts,' said Gary Maslow, child and adolescent psychiatrist.

The panel says the causes are many, including students spending more than a year in virtual learning during the pandemic.

Behavioral health analyst Sherika Hill said that the pandemic has exacerbated one's feeling of isolation and loneliness."

[30] ***The Truth About Lockdowns***
Rational Ground
July 6, 2021
https://rationalground.com/the-truth-about-lockdowns/

A list of links to authoritative studies and articles on the impact of lockdown policies. Categories include people suffering with other diseases, starvation and food insecurity, effects on children, domestic/sexual abuse, economy and poverty, mental health, suicides, and substance abuse.

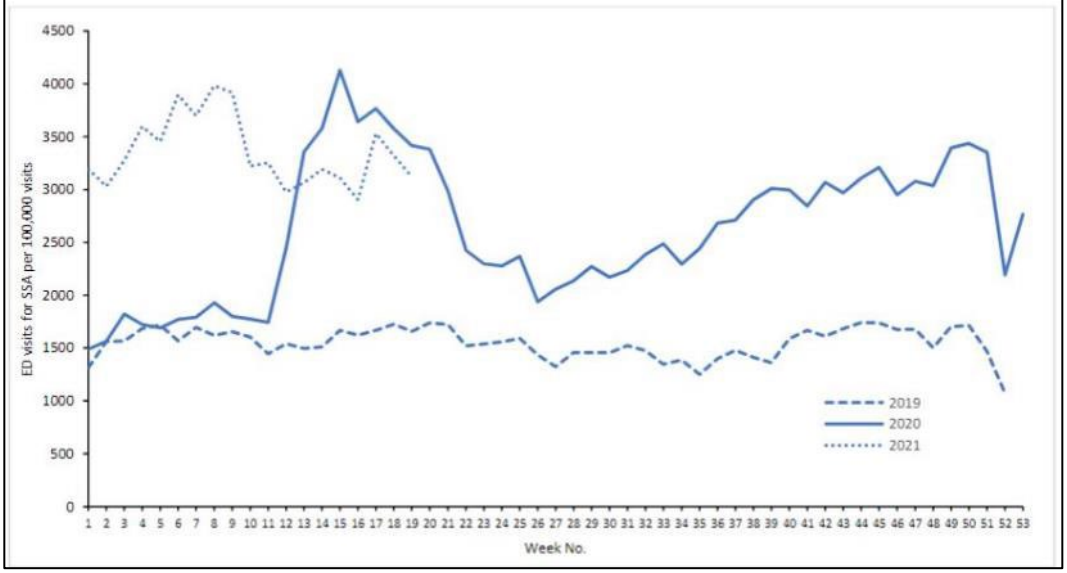
[31] **ADDED since 2/8/2022**
Emergency Department Visits for Suspected Suicide Attempts Among Persons Aged 12–25 Years Before and During the COVID-19 Pandemic — United States, January 2019–May 2021
Centers for Disease Control and Prevention
Ellen Yard, Lashmi Radhakrishnan, *et al*.
June 18, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/mm7024e1.htm

"Beginning in March 2020, the COVID-19 pandemic and response, which included physical distancing and stay-at-home orders, disrupted daily life in the United States. Compared with the rate in 2019, a **31% increase** in the proportion of mental health–related emergency department (ED) visits occurred among adolescents aged 12–17 years in 2020 [*emphasis added*]. In June 2020, 25% of surveyed adults aged 18–24 years reported experiencing suicidal ideation related to the pandemic in the past 30 days… [D]uring February 21–March 20, 2021, mean weekly ED visit counts for suspected suicide attempts were 50.6% higher among girls aged 12–17 years compared with the same period in 2019…

Among adolescents aged 12–17 years, mean weekly number of ED visits for suspected suicide attempts were 22.3% higher during summer 2020 and 39.1% higher during winter 2021 than during the corresponding periods in 2019, with a more pronounced increase among females. During winter 2021, ED visits for suspected suicide attempts were **50.6% higher** among females compared with the same period in 2019 [*emphasis added*]…. Among adolescents aged 12–17 years, the rate of ED visits for suspected suicide attempts also increased as the pandemic progressed (Supplementary Figure 1). Compared with the rate during the corresponding period in 2019, the rate of ED visits for suspected suicide attempts was 2.4 times as high during spring 2020, 1.7 times as high during summer 2020, and 2.1 times as high during winter 2021. This increase was driven largely by suspected suicide attempt visits among females."

SUPPLEMENTARY FIGURE 1. Weekly number of emergency department visits* for suspected suicide attempt† per 100,000 ED visits among persons aged 12–17 years, by sex — National Syndromic Surveillance Program, United States, January 1, 2019–May 15, 2021

A. Females



[32] ***Editor's Note – Cancer Review Issue***
Collateral Global
Jay Bhattacharya
June 1, 2021
https://collateralglobal.org/article/editors-note-4/

> "Lockdown-related diagnosis and treatment delays will result in long-term harms for cancer patients…
>
> To protect our health care systems, the media and some in public health created the impression in many that COVID is more deadly than cancer. This impression, unfortunately, led many cancer patients to skip their life-saving treatments. An American Cancer Society survey in May 2020 of cancer patients reported shocking numbers. Nearly eight out of ten cancer patients reported delays in care, with almost six out ten skipping doctor visits, one in four skipping imaging, and one in six missing surgery. **These are directly visible harms caused by the lockdown** [*emphasis added*]."

[33] ***The Impact of the COVID-19 Pandemic and Policy Responses on Excess Mortality***
National Bureau of Economic Research
Virat Agrawal, Jonathan H. Cantor, Neeraj Sood, and Christopher M. Whaley
June 2021
https://www.nber.org/system/files/working_papers/w28930/w28930.pdf

"**Abstract**: As a way of slowing COVID-19 transmission, many countries and U.S. states implemented shelter-in-place (SIP) policies. However, the effects of SIP policies on public health are a priori ambiguous as they might have unintended adverse effects on health. The effect of SIP policies on COVID-19 transmission and physical mobility is mixed. To understand the net effects of SIP policies, we measure the change in excess deaths following the implementation of SIP policies in 43 countries and all U.S. states…

Introduction: [W]e fail to find that SIP policies saved lives. To the contrary, we find a positive association between SIP policies and excess deaths. We find that following the implementation of SIP policies, **excess mortality increases** [*emphasis added*]…

If SIP were implemented when excess deaths were rising then the results … would be biased towards finding that SIP policies lead to excess deaths. However, we find the opposite: countries that implemented SIP policies experienced a decline in excess mortality prior to implementation compared to countries that did not implement SIP policies…

[T]he implementation of SIP policies does not appear to have met the aim of reducing excess mortality. There are several potential explanations for this finding. First, it is possible that SIP policies do not slow COVID-19 transmission… Second, it is possible that SIP policies increased deaths of despair due to economic and social isolation effects of SIP policies. Recent estimates in the U.S between March and August 2020 show that drug overdoses, homicides, and unintentional injuries increased in 2020, while suicides declined (Faust et al. 2021). Third, existing studies suggest that SIP policies led to a reduction in non-COVID-19 health care, which might have contributed to an increase in non-COVID-19 deaths."

[34] ***Covid Lockdown Cost/Benefits: A Critical Assessment of the Literature***
Simon Fraser University
Douglas W. Allen
April 2021
https://www.sfu.ca/~allen/LockdownReport.pdf?

"**Abstract**: An examination of over 80 Covid-19 studies reveals that many relied on assumptions that were false, and which tended to over-estimate the benefits and under-estimate the costs of lockdown. As a result, most of the early cost/benefit studies arrived at conclusions that were refuted later by data, and which rendered their cost/benefit findings incorrect. Research done over the past six months has shown that lockdowns have had, at best, a marginal effect on the number of Covid-19 deaths… The limited effectiveness of lockdowns explains why, after one year, the unconditional cumulative deaths per million, and the pattern of daily deaths per million, is not negatively correlated with the stringency of lockdown across countries."

[35] ***The Backward Art of Slowing the Spread? Congregation Efficiencies during COVID-19***
Casey B. Mulligan
April 2021
https://bfi.uchicago.edu/wp-content/uploads/2021/04/BFI_WP_2021-51-1.pdf

"Micro evidence contradicts the public-health ideal in which households would be places of solitary confinement and zero transmission. Instead, the evidence suggests that 'households show the highest transmission rates' and that 'households are high-risk settings for the transmission of [COVID-19].'"

[36] ***A guideline to limit indoor airborne transmission of COVID-19***
Proceedings of the National Academy of Sciences (PNAS)
Martin Z. Bazant and John W.M. Bush (Massachusetts Institute of Technology)
April 15, 2021
https://www.pnas.org/content/118/17/e2018995118

"**Abstract**: The current revival of the American economy is being predicated on social distancing, specifically the Six-Foot Rule, a guideline that offers little protection from pathogen-bearing aerosol droplets sufficiently small to be continuously mixed through an indoor space…

There is now overwhelming evidence that indoor airborne transmission associated with relatively small, micron-scale aerosol droplets plays a dominant role in the spread of COVID-19, especially for so-called 'superspreading events,' which invariably occur indoors. For example, at the 2.5-h-long Skagit Valley Chorale choir practice that took place in Washington State on March 10, some 53 of 61 attendees were infected, presumably not all of them within 6 ft of the initially infected individual. Similarly, when 23 of 68 passengers were infected on a 2-h bus journey in Ningbo, China, their seated locations were uncorrelated with distance to the index case. Airborne transmission was also implicated in the COVID-19 outbreak between residents of a Korean high-rise building whose apartments were linked via air ducts. Studies have also confirmed the presence of infectious SARS-CoV-2 virions in respiratory aerosols suspended in air samples collected at distances as large as 16 ft from infected patients in a hospital room. Further evidence for the dominance of indoor airborne transmission has come from an analysis of 7,324 early cases outside the Hubei Province, in 320 cities across mainland China. The authors found that all clusters of three or more cases occurred indoors, **80% arising inside apartment homes** and **34% potentially involving public transportation**; only a single transmission was recorded outdoors [*emphasis added*]."

[37] ***Impacts of COVID-19 on global poverty, food security, and diets: Insights from global model scenario analysis***
Agricultural Economics (International Policy Food Research Institute)
David Laborde, Will Martin, and Rob Vos
April 8, 2021
https://onlinelibrary.wiley.com/doi/10.1111/agec.12624

"**Abstract**: This study assesses the impact of coronavirus disease 2019 (COVID-19) on poverty, food insecurity, and diets, accounting for the complex links between the crisis and the incomes and living costs of vulnerable households. Key elements are impacts on labor supply, effects of social distancing, shifts in demand from services involving close contact, increases in the cost of logistics in food and other supply chains, and reductions in savings and investment. These are examined using IFPRI's global general equilibrium model linked to epidemiological and household models. The simulations suggest that the global recession caused by COVID-19 will be much deeper than that of the 2008–2009 financial crisis. The increases in poverty are concentrated in South Asia and sub-Saharan Africa with impacts harder in urban areas than in rural. **The COVID-19-related lockdown measures explain most of the fall in output**, whereas declines in savings soften the adverse impacts on food consumption. **Almost 150 million people are projected to fall into extreme poverty** and **food insecurity** [*emphasis added*]. Decomposition of the results shows that approaches assuming uniform income shocks would underestimate the impact by as much as one-third,

emphasizing the need for the more refined approach of this study."

[38] **ADDED since 2/8/2022**

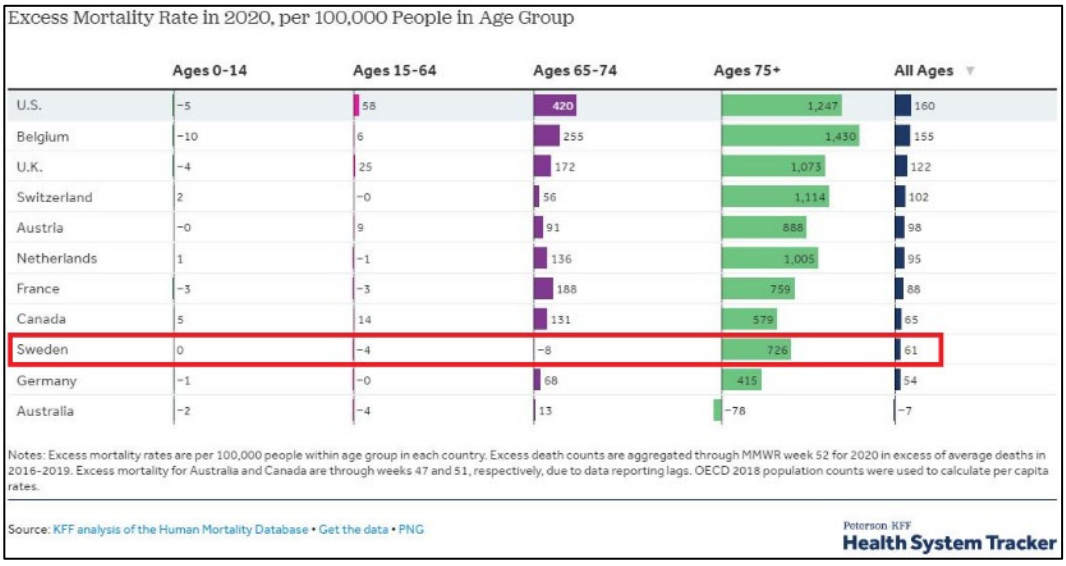
COVID-19 pandemic-related excess mortality and potential years of life lost in the U.S. and peer countries

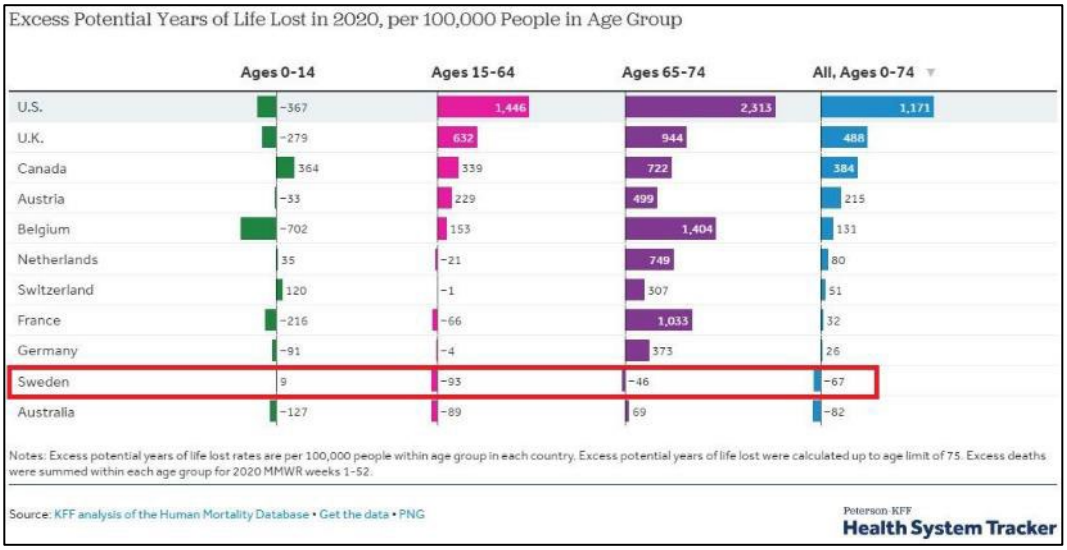
Peterson Center on Healthcare and Kaiser Family Foundation
Krutika Amin and Cynthia Cox
April 7, 2021
https://www.healthsystemtracker.org/brief/covid-19-pandemic-related-excess-mortality-and-potential-years-of-life-lost-in-the-u-s-and-peer-countries/

"In this brief, we review excess death rates in the U.S. and peer countries by age groups to examine how the pandemic has affected excess mortality rate among younger people. We look specifically at the excess deaths that arose in 2020 to examine how the age at death during the pandemic has differed between the U.S. and peer nations. We also estimate the excess potential years of life lost (a measure of 'premature excess death') during the pandemic…

We find that, among similarly large and wealthy countries, the U.S. had among the highest excess mortality rates in 2020, and younger people were more likely to have died due to the pandemic in the U.S. than younger people in other countries. With a much higher rate of death among people under age 75, the U.S. had the highest increase in premature deaths due the pandemic in 2020. Before the pandemic, the U.S. already had the highest premature death rate of peer nations, by far. We find that per capita premature excess death rate in the U.S. was over twice as high as the next closest peer country, the U.K…

In 2020, the U.S. had the highest pandemic-related mortality and potential years of life lost among peer countries."

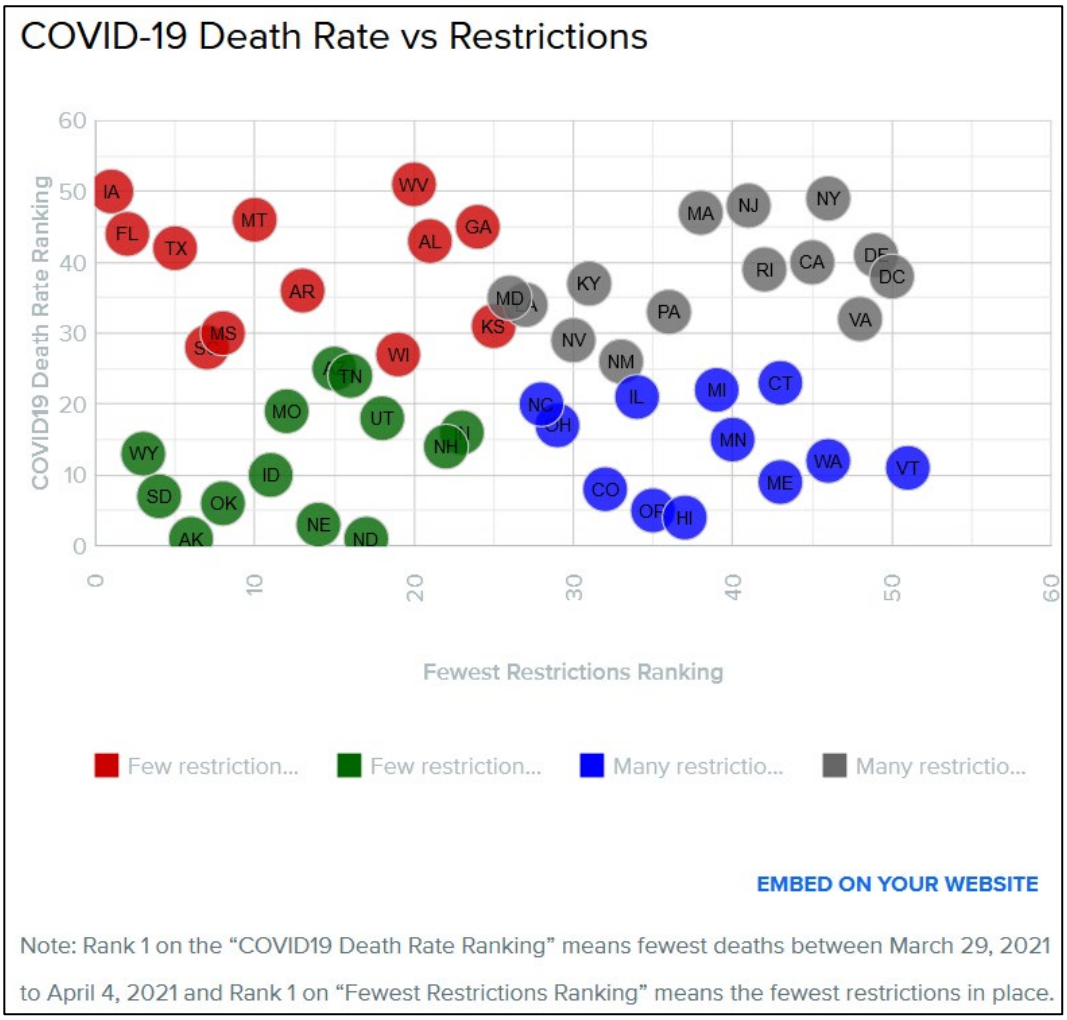




[39] ***States with the Fewest Coronavirus Restrictions***
WalletHub
Adam McCann
April 6, 2021
https://wallethub.com/edu/states-coronavirus-restrictions/73818

> "In order to determine the states with the fewest coronavirus restrictions, WalletHub compared the 50 states and the District of Columbia across 13 key metrics. Our data set ranges from whether restaurants are open to whether the state has required face masks in public and workplace temperature screenings. Read on for the state ranking, additional insight from a panel of experts and a full description of our methodology…
>
> **Sources**: Data used to create this ranking were collected from the U.S. Census Bureau, the U.S. Bureau of Labor Statistics, the Kaiser Family Foundation, Ballotpedia, Editorial Projects in Education, Centers for Disease Control and Prevention, National Restaurant Association, Littler Mendelson, Husch Blackwell and Ogletree Deakins."

US States



[40] ***Slightly More Than 6 in 10 U.S. Adults (61%) Report Undesired Weight Change Since Start of Pandemic***
American Psychological Association
March 2021
https://www.apa.org/news/press/releases/2021/03/march-weight-change

> "18% of U.S. adults report undesired weight loss, with an average weight loss of 26 lbs. 42% of U.S. adults report undesired weight gain, with an average gain of 29 lbs."

[41] ***Sweden saw lower 2020 death spike than much of Europe – data***
Reuters
Johan Ahlander
March 24, 2021
https://www.reuters.com/article/us-health-coronavirus-europe-mortality-idUSKBN2BG1R9

> "Sweden, which has shunned the strict lockdowns that have choked much of the global economy, emerged from 2020 with a smaller increase in its overall mortality rate than most European countries, an analysis of official data sources showed…

Preliminary data from EU statistics agency Eurostat compiled by Reuters showed Sweden had 7.7% more deaths in 2020 than its average for the preceding four years. Countries that opted for several periods of strict lockdowns, such as Spain and Belgium, had so-called excess mortality of 18.1% and 16.2% respectively…

Sweden's excess mortality also came out at the low end of the spectrum in a separate tally of Eurostat and other data released by the UK's Office for National Statistics last week."

[42] **#The Price of Panic**
Last updated March 21, 2021
A collection of links illustrating the derivative harms incurred by policy responses to the COVID-19 pandemic. Categories include 'Hunger & Poverty,' 'Death from Other Diseases,' 'Harm to Children,' 'Anxiety, Depression & Suicides,' and 'Oppression.'
https://thepriceofpanic.com/

"The negative effects of lockdown are too often dismissed as small sacrifices, necessary to keep a highly deadly disease from spreading. These sacrifices are, in fact, neither necessary nor small. The disease is a serious threat to a minority of the population that *can* be protected without lockdowns. All too often, when major harms become hard to ignore, they are lamented as damage caused by COVID-19 itself, even though it is our panic-driven measures that are to blame. This is an effort to bring focus to the magnitude of suffering taking place around us because of lockdowns."

[43] ***Dr. John Lee: My darkest predictions have come true... the effects of Covid lockdowns are catastrophic***
Daily Mail
Dr. John Lee, former professor of pathology and UK National Health Service (NHS) consultant pathologist
March 21, 2021
https://www.dailymail.co.uk/debate/article-9386953/DR-JOHN-LEE-darkest-predictions-come-true-effects-lockdowns-catastrophic.html

"One year on from the start of the first lockdown, the brutal price of this drastic policy is all too obvious. Amid battered public finances, rising unemployment and widespread business failures, entire sectors of the economy have been devastated…

Covid-dominated Britain is a bleak unnatural land where all our ordinary freedoms are locked away…

What is certain is the damage caused by lockdowns on every front, including economic meltdown, poor mental health, the inhumane neglect of the elderly and dislocated family relationships.

The greatest paradox of our Covid obsession is that it has undermined other forms of healthcare by warping the priorities of the NHS.

Tragically, tens of thousands of serious conditions, including cancer, have gone undiagnosed, while treatments are being delayed, operations abandoned and screening programmes curtailed."

[44] **ADDED since 2/8/2022**

Covid-19 disruptions killed 228,000 children in South Asia, says UN report

BBC News
March 17, 2021
https://www.bbc.com/news/world-asia-56425115

> "The disruption in healthcare services caused by Covid-19 may have led to an estimated 239,000 maternal and child deaths in South Asia, according to a new UN report…
>
> Many countries, including those in South Asia, responded to the pandemic with **stringent lockdowns**. While hospitals, pharmacies and grocers remained open, almost everything else shut down.
>
> The report - Direct and Indirect Effects of Covid-19 Pandemic and Response in South Asia - examines the effect of these government strategies on healthcare, social services, including schools, and the economy.
>
> It estimates that there have been **228,000 additional deaths of children under five** in these six countries due to crucial services, ranging from nutrition benefits to immunisation, being halted.
>
> It says the number of children being treated for severe malnutrition fell by more than 80% in Bangladesh and Nepal, and immunisation among children dropped by 35% and 65% in India and Pakistan respectively.
>
> The report also says that child mortality rose the highest in India in 2020 - up by 15.4% - followed by Bangladesh at 13%. Sri Lanka saw the sharpest increase in maternal deaths - 21.5% followed by Pakistan's 21.3%...
>
> The full effect of the pandemic - and ensuing lockdowns - is just starting to become clear as countries take stock of their public health and education programmes."

[45] ***Global rise in childhood mental health issues amid pandemic***

AP News
John Leicester
March 12, 2021
https://apnews.com/article/global-rise-childhood-mental-health-pandemic-8392ceff77ac8e1e0f90a32214e7def1

> "For doctors who treat them, the pandemic's impact on the mental health of children is increasingly alarming. The Paris pediatric hospital caring for Pablo has seen a doubling in the number of children and young teenagers requiring treatment after attempted suicides since September.
>
> Doctors elsewhere report similar surges, with children — some as young as 8 — deliberately running into traffic, overdosing on pills and otherwise self-harming. In Japan, child and adolescent suicides hit record levels in 2020, according to the Education Ministry.
>
> Pediatric psychiatrists say they're also seeing children with coronavirus-related phobias, tics and eating disorders, obsessing about infection, scrubbing their hands raw, covering their bodies with disinfectant gel and terrified of getting sick from food.

Also increasingly common, doctors say, are children suffering panic attacks, heart palpitations and other symptoms of mental anguish, as well as chronic addictions to mobile devices and computer screens…

'This is an international epidemic, and we are not recognizing it,' [Dr. David] Greenhorn said in a telephone interview…

At Robert Debré, the psychiatric unit typically used to see about 20 attempted suicide cases per month involving children aged 15 and under. Not only has that number now doubled in some months since September, but some children also seem ever-more determined to end their lives, [Dr. Richard] Delorme said.

'We are very surprised by the intensity of the desire to die among children who may be 12 or 13 years old,' he said. 'We sometimes have children of 9 who already want to die. And it's not simply a provocation or a blackmail via suicide. It is a genuine wish to end their lives.'

'The levels of stress among children are truly massive,' he said."

[46] ***COVID-19 Lockdown Policies: An Interdisciplinary Review***
University of Greenwich
Oliver Robinson
March 10, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3782395

"**Abstract**: Lockdown interventions employed in response to the COVID-19 pandemic have been evaluated via research at biomedical, economic, psychological, and ethical levels of analysis. The aim of this article is to integrate these perspectives into an interdisciplinary biopsychosocial review. Biomedical evidence from the early months of the pandemic suggests that lockdowns were associated with a reduced viral reproductive rate, but that less restrictive measures also had a similar effect. Lockdowns are associated with reduced mortality in epidemiological modelling studies but not in studies based on empirical data from the Covid-19 pandemic. Psychological research supports the proposition that lengthy lockdowns may exacerbate stressors such as social isolation and unemployment that have been shown to be strong predictors of falling ill if exposed to a respiratory virus. Studies at the economic level of analysis points to the possibility that deaths associated with economic harms or underfunding of other health issues may outweigh the deaths that lockdowns save, and that the extremely high financial cost of lockdowns may have negative implications for overall population health in terms of diminished resources for treating other conditions."

[47] ***Stay-at-home policy is a case of exception fallacy: an internet-based ecological study***
Nature - Scientific Reports
R.F. Savaris, G. Pumi, J. Dalzochio, and R. Kunst
March 5, 2021
https://www.nature.com/articles/s41598-021-84092-1

"**Abstract**: A recent mathematical model has suggested that staying at home did not play a dominant role in reducing COVID-19 transmission. The second wave of cases in Europe, in regions that were considered as COVID-19 controlled, may raise some concerns. Our objective was to assess the association between staying at home (%) and the reduction/increase in the number of deaths due to COVID-19 in several regions in the world. In this ecological study, data from www.google.com/covid19/mobility/, ourworldindata.org and

covid.saude.gov.br were combined… After preprocessing the data, 87 regions around the world were included, yielding 3741 pairwise comparisons for linear regression analysis. Only 63 (1.6%) comparisons were significant. With our results, we were not able to explain if COVID-19 mortality is reduced by staying at home in ~ 98% of the comparisons after epidemiological weeks 9 to 34.

Discussion: We were not able to explain the variation of deaths/million in different regions in the world by social isolation, herein analyzed as differences in staying at home, compared to baseline… These findings are in accordance with those found by Klein et al… Likewise, Chaudry et al. made a country-level exploratory analysis, using a variety of socioeconomic and health-related characteristics, similar to what we have done here, and reported that **full lockdowns and wide-spread testing were not associated with COVID-19 mortality** per million people [*emphasis added*]."

[48] **White Paper: *The Impact of COVID-19 on Pediatric Mental Health***
FAIR Health
March 2, 2021
https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/The%20Impact%20of%20COVID-19%20on%20Pediatric%20Mental%20Health%20-%20A%20Study%20of%20Private%20Healthcare%20Claims%20-%20A%20FAIR%20Health%20White%20Paper.pdf

"**Summary**: The COVID-19 pandemic has had a profound impact on mental health, particularly on that of young people. Defining the pediatric population as individuals aged 0-22 years, and focusing on the age groups 13-18 years and 19-22 years, FAIR Health studied the effects of the pandemic on US pediatric mental health. To do so, FAIR Health analyzed data from its database of over 32 billion private healthcare claim records, tracking month-by-month changes from January to November 2020 compared to the same months in 2019…

- In March and April 2020, mental health claim lines for individuals aged 13-18, as a percentage of all medical claim lines, approximately doubled over the same months in the previous year…
- Claim lines for intentional self-harm as a percentage of all medical claim lines in the 13-18 age group **increased 90.71 percen**t in March 2020 compared to March 2019 [*emphasis added*]. The increase was even larger when comparing April 2020 to April 2019, nearly doubling (99.83 percent).
- Comparing August 2019 to August 2020 in the Northeast, for the age group 13-18, there was a **333.93 percent increase** in intentional self-harm claim lines as a percentage of all medical claim lines [*emphasis added*], a rate higher than that in any other region in any month studied for that age group…
- For the age group 13-18, claim lines for overdoses increased 94.91 percent as a percentage of all medical claim lines in March 2020 and 119.31 percent in April 2020 over the same months the year before. Claim lines for substance use disorders also increased as a percentage of all medical claim lines in March (64.64 percent) and April (62.69 percent) 2020 as compared to their corresponding months in 2019…

- For the age group 13-18, in April 2020, claim lines for generalized anxiety disorder increased 93.6 percent as a percentage of all medical claim lines over April 2019, while major depressive disorder claim lines increased 83.9 percent and adjustment disorder claim lines 89.7 percent."

[49] ***Swedish researchers: Anti-corona restrictions have killed as many people as the virus itself***
Norway Today
Robin Ivan Capar
March 1, 2021
https://norwaytoday.info/news/swedish-researchers-anti-corona-restrictions-have-killed-as-many-people-as-the-virus-itself/

"SVT [Swedish television] asked professors Stefan Swartling Peterson and Anna Mia Ekström [*Karolinska Institutet*] to calculate how many people died due to the anti-corona restrictions.

They believe the number is at least 2.5 million.

The restrictions have first and foremost hit the poorer parts of the world and struck young people, the researchers believe, pointing to children who died of malnutrition and various diseases. They also pointed to adults who died of diseases that could have been treated."

[50] ***COVID-19: How lockdown is taking its toll on millions caught in battle with addiction***
Sky News (UK)
Ashna Hurynag
February 13, 2021
https://news.sky.com/story/covid-19-how-lockdown-is-taking-its-toll-on-millions-caught-in-battle-with-addiction-12216562

"The families of those with substance abuse issues have spoken of the immense pressure and danger this lockdown is putting on their lives.

The isolation of lockdown is heightening the trauma and mental health issues associated with addiction…

The Action on Addiction charity says it saw an 86% rise in the number of people seeking help this January compared with last year."

[51] ***Damage to children's mental health caused by Covid crisis could last for years without a large-scale increase for children's mental health services***
The Children's Commissioner for England
January 28, 2021
https://www.childrenscommissioner.gov.uk/2021/01/28/damage-to-childrens-mental-health-caused-by-covid-crisis-could-last-for-years-without-a-large-scale-increase-for-childrens-mental-health-services/

"A large study, undertaken by the NHS in July 2020, found that clinically significant **mental health conditions amongst children had risen by 50%** compared to three years earlier. A staggering 1 in 6 children now have a probable mental health condition [*emphasis added*]…

Anne Longfield, Children's Commissioner for England, said:

'It is widely accepted that lockdown and school closures have had a detrimental effect on the mental health of many children. Since the NHS study in July 2020 estimating one in six children in England have a probable mental health condition, we have had another long lockdown. Sadly, this will be causing even more damage to many children's mental wellbeing and putting even greater strains on mental health services, potentially for years to come.'"

[52] ***Assessing mandatory stay-at-home and business closure effects on the spread of COVID-19***
European Journal of Clinical Investigation
Eran Bendavid, Christopher Oh, Jay Bhattacharya, and John Ioannidis
January 5, 2021
https://onlinelibrary.wiley.com/doi/10.1111/eci.13484

"**Results**: … **In none of the 8 countries and in none out of the 16 comparisons** (against Sweden or South Korea) were the effects of mrNPIs [*more restrictive nonpharmaceutical interventions*] significantly negative (beneficial) [*emphasis added*]."

"**Discussion**: In the framework of this analysis, there is no evidence that more restrictive non-pharmaceutical interventions ('lockdowns') contributed substantially to bending the curve of new cases in England, France, Germany, Iran, Italy, the Netherlands, Spain, or the United States in early 2020. By comparing the effectiveness of NPIs on case growth rates in countries that implemented more restrictive measures with those that implemented less restrictive measures, the evidence points away from indicating that mrNPIs (major interventions) provided additional meaningful benefit above and beyond lrNPIs (light interventions)…

In summary, we fail to find strong evidence supporting a role for more restrictive NPIs in the control of COVID in early 2020. We do not question the role of all public health interventions, or of coordinated communications about the epidemic, but we fail to find an additional benefit of stay-at-home orders and business closures. The data cannot fully exclude the possibility of some benefits. However, even if they exist, these benefits may not match the numerous harms of these aggressive measures. More targeted public health interventions that more effectively reduce transmissions may be important for future epidemic control without the harms of highly restrictive measures."

[53] ***Lockdown Effects on Sars-CoV-2 Transmission – The evidence from Northern Jutland Aarhus University and Technical University of Denmark***
Kasper Planeta Kepp and Christian Bjornskov
January 4, 2021
https://www.medrxiv.org/content/10.1101/2020.12.28.20248936v1.full-text

"**Abstract**: … Here, we analyse the unique case-controlled epidemiological dataset arising from the selective lockdown of parts of Northern Denmark, but not others, as a consequence of the spread of mink-related mutations in November 2020. Our analysis shows that while infection levels decreased, they did so before lockdown was effective, and infection numbers also decreased in neighbour municipalities without mandates."

[54] ***White Paper: Covid Recovery – A Scientific Approach***
COVID-19 Ireland
December 2020
https://covidrecovery.ie/
Medical Signatories:
https://drive.google.com/file/d/1Mfc85i17Z9d2CyLzlf0bOqin3vbXbQfd/view
About: "Our goal is to bring objectivity and balance to the discussion around management of the COVID19 Pandemic. Our values are based on the time honoured clinical mantra of 'first, do no harm.' We are gravely concerned with the complete absence of reasonable debate on the subject within our media. As clinicians, we see first hand the other side of the 'daily case numbers' update: depression, fear, isolation, unemployment, the destruction of hope etc. We are committed to proposing reasonable and workable solutions to the problems faced by our society at this time and urge avoidance of the destructive and singular path of cyclical lockdown. Directly below is our white paper, which is a medically composed paper, written and verified by doctors and medical practitioners on the effects of lockdown, and the path out of this pandemic."

> "**Lockdown Interventions – are there convincing real-world benefits for morbidity / mortality?** … We now have the benefit of experience and multiple published analyses reflecting real-world data and outcomes. A recent paper in The Lancet showed no correlation between lockdown measures and mortality outcomes: 'Rapid border closures, full lockdowns, and wide-spread testing were not associated with COVID-19 mortality per million people.' Notably, a large number of published preprint analyses converge on lockdowns having a minimal beneficial effect on mortality outcomes. There is a dearth of published evidence indicating that lockdowns reduce overall mortality; a significant concern in itself, given the enormous negative impacts of lockdown. Sweden is particularly notable as a 'control' country which largely followed the 2019 WHO Pandemic Guidelines, rather than pursuing the very new lockdown approach. With this strategy, they experienced a similar mortality impact to other European countries, when various key factors are accounted for."

> "**Lockdown Interventions – what is the evidence for costs far exceeding any benefits?** It is critical that we now apply our understanding of these analyses and ask the question: Do the costs of lockdown outweigh (possibly greatly) - the benefits of lockdown? A recent paper published in the British Medical Journal concluded that lockdown interventions could increase COVID-19 mortality rates over the long term. Another analysis in preprint proposes the same unintended consequences. It is crucial that we consider these latest analyses, and face the possibility that lockdown interventions could result in more COVID-19 deaths than if we simply followed the WHO 2019 pandemic guidelines, as Sweden did."

[55] ***Lockdowns Do Not Control the Coronavirus: The Evidence***
AIER
December 19, 2020
A review of the findings from 35 studies examining the effectiveness and consequences of lockdown policies, with key excerpts and related links.
https://www.aier.org/article/lockdowns-do-not-control-the-coronavirus-the-evidence/

> "The use of universal lockdowns in the event of the appearance of a new pathogen has no precedent. It has been a science experiment in real time, with most of the human population used as lab rats. The costs are legion…

The pro-lockdown evidence is shockingly thin, and based largely on comparing real-world outcomes against dire computer-generated forecasts derived from empirically untested models, and then merely positing that stringencies and 'nonpharmaceutical interventions' account for the difference between the fictionalized vs. the real outcome. The anti-lockdown studies, on the other hand, are evidence-based, robust, and thorough, grappling with the data we have (with all its flaws) and looking at the results in light of controls on the population."

[56] ***Effects of non-pharmaceutical interventions on COVID-19: A Tale of Three Models***
Vincent Chin (University of Sydney), John P.A. Ioannidis (Stanford University), Martin A. Tanner (Northwestern University), and Sally Cripps (University of Sydney)
December 10, 2020
https://www.medrxiv.org/content/10.1101/2020.07.22.20160341v3.full-text

"**Objective**: To compare the inference regarding the effectiveness of the various non-pharmaceutical interventions (NPIs) for COVID-19 obtained from different SIR [*susceptible-infected-removed*] models…

Conclusions: Inferences on effects of NPIs are non-robust and highly sensitive to model specification. Claimed benefits of lockdown appear grossly exaggerated."

[57] ***Covid-19 Mortality: A Matter of Vulnerability Among Nations Facing Limited Margins of Adaptation***
Frontiers in Public Health
Quentin De Larochelambert, Andy Marc, Juliana Antero, Eric Le Bourg, and Jean-François Toussaint
November 19, 2020
https://www.frontiersin.org/articles/10.3389/fpubh.2020.604339/full

"**Results**: Higher Covid death rates are observed in the [25/65°] latitude and in the [−35/−125°] longitude ranges. The national criteria most associated with death rate are life expectancy and its slowdown, public health context (metabolic and non-communicable diseases (NCD) burden vs. infectious diseases prevalence), economy (growth national product, financial support), and environment (temperature, ultra-violet index). Stringency of the measures settled to fight pandemia, including lockdown, did not appear to be linked with death rate.

Conclusion: Countries that already experienced a stagnation or regression of life expectancy, with high income and NCD rates, had the highest price to pay. This burden was not alleviated by more stringent public decisions. Inherent factors have predetermined the Covid-19 mortality: understanding them may improve prevention strategies by increasing population resilience through better physical fitness and immunity."

[58] ***The long-term effects of school closures***
Centre for Economic Policy Research (Goethe University Frankfurt)
Nicola Fuchs-Schündeln, Dirk Krueger, Alexander Ludwig, and Irina Popova
November 12, 2020
https://voxeu.org/article/long-term-effects-school-closures

> "[Our] results suggest that school and childcare closures have significant negative long-term consequences on the human capital and welfare of the affected children, especially those from disadvantaged socioeconomic backgrounds. The loss in schooling and associated human capital accumulation is harder to offset the longer the crisis lasts."

[59] ***The Mystery of Taiwan***
AIER
Amelia Janaskie
November 7, 2020
https://www.aier.org/article/the-mystery-of-taiwan/

> "In terms of stringency, Taiwan ranks among the lowest in the world, with fewer controls than Sweden and far lower than the U.S… The government did test at the border and introduce some minor controls but nowhere near that of most counties. In general, Taiwan rejected lockdown in favor of maintaining social and economic functioning.
>
> How did Taiwan fare in terms of cases? Taiwan has seen 573 cases, which is remarkably low for a country with a population of close to 24 million and a population density of 1,739 people per square mile.
>
> The Taiwanese case reveals something extraordinary about pandemic response. As much as public-health authorities imagine that the trajectory of a new virus can be influenced or even controlled by policies and responses, the current and past experiences of coronavirus illustrate a different point. The severity of a new virus might have far more to do with endogenous factors within a population rather than the political response. According to the lockdown narrative, Taiwan did almost everything 'wrong' but generated what might in fact be the best results in terms of public health of any country in the world."

[60] **Interview with Dr. David Nabarro, WHO Special Envoy on COVID-19**
The Spectator
October 9, 2020
https://twitter.com/spectator/status/1314573157827858434

> "We in the World Health Organization do not advocate lockdowns as the primary means of control of this virus… It seems we may well have a doubling of world poverty by next year. We may well have at least a doubling of child malnutrition… This is a terrible, ghastly global catastrophe."

[61] ***Alcoholism in the time of coronavirus***
BBC
October 5, 2020
https://www.bbc.com/news/uk-england-essex-53684700

> "Alcohol abuse has increased during the coronavirus pandemic, according to the British Liver Trust, which has reported a 500% rise in calls to its helpline since lockdown began in March."

[62] ***The Great Barrington Declaration***
Martin Kulldorff, Sunetra Gupta, Jay Bhattacharya, *et al*.
October 4, 2020
https://gbdeclaration.org/
Signatures: https://gbdeclaration.org/view-signatures/
Signed by 14,879 medical & health scientists and 43,804 medical practitioners, as of September 4, 2021.

> "As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection... Current lockdown policies are producing devastating effects on short and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden."

[63] ***Undoing the untold harms of COVID-19 on young people: a call to action***
University of Exeter
Matthew Owens
September 10, 2020
https://thefatemperor.com/wp-content/uploads/2020/11/PDF-UK-Site-Reachwell.org-Mental-Health-Evidence-Based.com_.pdf

> "Some 80% of the 2000 young people with a history of mental health needs surveyed by the charity Young Minds agreed that the COVID-19 crisis had worsened their mental health[3]…
>
> [T]he risk of mortality is moderated sharply by advancing years such that, compared to young people (0-19), being 80 years old or over increases the odds of death more than 80-fold[5]."
>
> "Although the risk posed by SARS-CoV-2 is very low, there is unfortunately already a wealth of evidence suggesting that the lockdown is causing **untold harms to children and young people** [*emphasis added*]. Compared to other age groups, children's mental health has deteriorated the most during this time, which may also cause long-term damage In addition, reported physical abuse to children rose by half during the lockdown, children's physical conditions have worsened through delayed presentation to services and most pupils are thought by teachers to be behind in their school learning (by an estimated 3 months)."

[64] ***Child Maltreatment during the COVID-19 Pandemic: Consequences of Parental Job Loss on Psychological and Physical Abuse Towards Children***
Child Abuse & Neglect (University of Texas, San Antonio)
Monica Lawson, Megan H. Piel, and Michaela Simon
September 4, 2020
https://www.sciencedirect.com/science/article/pii/S0145213420303641

> "**Discussion**: There is immense concern that the COVID-19 pandemic will have unforeseen consequences for children's safety and well-being. Numerous public health organizations point to the economic downturn in the United States, and parental job loss specifically, as amplifying risk for child abuse (Substance Abuse & Mental Health Services Administration, 2020; The Alliance for Child Protection in Humanitarian Action, 2020; WHO Global, 2020). Consistent with the study hypotheses and prior observations of increased rates of child abuse during economic crises (Brooks-Gunn et al., 2013; Schenck-Fontaine et al., 2017), the current investigation identified parental job loss during the COVID-19 pandemic as a **robust predictor of psychological maltreatment and physical abuse towards children** during the pandemic [*emphasis added*]... The findings support growing concerns that the economic conditions caused by the COVID-19 pandemic will impact children's well-being and are consistent with ecological theories regarding the etiology of child maltreatment."

[65] ***Domestic abuse surged in lockdown, Panorama investigation finds***
The Guardian
Henry McDonald
August 16, 2020
https://theknowledgeexchangeblog.com/2020/09/28/domestic-violence-during-quarantine-the-hidden-crime-of-lockdown/

> "The coronavirus crisis has dramatically compounded domestic violence against women, new research has revealed.
>
> Two-thirds of women in abusive relationships have suffered more violence from their partners during the pandemic, according to an investigation by the BBC's Panorama.
>
> Three-quarters of victims also say the lockdown has made it harder for them to escape their abusers.
>
> The joint investigation by Panorama and Women's Aid is the first in-depth study into how the nationwide shutdown in response to Covid-19 has impacted victims of domestic abuse."

[66] ***Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020***
Centres for Disease Control and Prevention (CDC)
Mark E. Czeisler, Rashon I. Lane, *et al*.
August 14, 2020
https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm

> "**What is added by this report?** During June 24–30, 2020, U.S. adults reported considerably elevated adverse mental health conditions associated with COVID-19. Younger adults, racial/ethnic minorities, essential workers, and unpaid adult caregivers reported having experienced disproportionately worse mental health outcomes, increased substance use, and elevated suicidal ideation."

"To assess mental health, substance use, and suicidal ideation during the pandemic, representative panel surveys were conducted among adults aged ≥18 years across the United States during June 24–30, 2020. Overall, **40.9% of respondents reported at least one adverse mental or behavioral health condition**, including symptoms of anxiety disorder or depressive disorder (30.9%), symptoms of a trauma- and stressor-related disorder (TSRD) related to the pandemic† (26.3%), and having started or increased substance use to cope with stress or emotions related to COVID-19 (13.3%). The **percentage of respondents who reported having seriously considered suicide in the 30 days before completing the survey (10.7%)** was significantly higher among respondents aged 18–24 years (**25.5%**), minority racial/ethnic groups (Hispanic respondents [**18.6%**], non-Hispanic black [black] respondents [**15.1%**]), self-reported unpaid caregivers for adults (**30.7%**), and essential workers (**21.7%**) [*emphasis added*]…

At least one adverse mental or behavioral health symptom was reported by more than one half of respondents who were aged 18–24 years (74.9%) and 25–44 years (51.9%), of Hispanic ethnicity (52.1%), and who held less than a high school diploma (66.2%), as well as those who were essential workers (54.0%), unpaid caregivers for adults (66.6%), and who reported treatment for diagnosed anxiety (72.7%), depression (68.8%), or PTSD (88.0%) at the time of the survey."

[67] ***"Stay at Home, Protect the National Health Service, Save Lives": A cost benefit analysis of the lockdown in the United Kingdom***
International Journal of Clinical Practice
David K. Miles, Michael Stedman, and Adrian H. Heald
August 13, 2020
https://onlinelibrary.wiley.com/doi/10.1111/ijcp.13674

"**Conclusion**: There is a need to normalise how we view COVID-19 because its costs and risks are comparable to other health problems (such as cancer, heart problems, diabetes) where governments have made resource decisions for decades. Treating possible future COVID-19 deaths as if nothing else matters is going to lead to bad outcomes. Good decision making does not mean paying little attention to the collateral damage that comes from responding to a worst-case COVID-19 scenario.

The lockdown is a public health policy and we have valued its impact using the tools that guide health care decision [*sic*] in the UK public health system. On that basis and taking a wide range of scenarios of costs and benefits of severe restrictions, we find the lockdown has consistently generated costs that are greater—and often dramatically greater—than possible benefits."

[68] **ADDED since 2/8/2020**
Reset the Table: Meeting the Moment to Transform the U.S. Food System
Rockefeller Foundation
July 28, 2020
https://www.rockefellerfoundation.org/wp-content/uploads/2020/07/RF-FoodPolicyPaper_Final2.pdf

> "**Foreword**: America faces a hunger and nutrition crisis unlike any this country has seen in generations. Today 14 million children are missing meals on a regular basis–a statistic that's three times worse than the Great Recession and **five times worse than before the Covid-19 pandemic**–as parents, who often skip meals themselves in order to prioritize feeding their kids, can no longer protect their children from hunger. It's even worse for Latino and Black families, who have seen rates of nutrition insecurity spike to 25 percent and 30 percent, respectively. In the wealthiest country in the world, this is simply unconscionable...
>
> **School closures put 30 million students at risk** of losing the meals they need to learn and thrive."

[69] ***Child malnutrition and COVID-19: the time to act is now***
The Lancet
Henrietta H Fore (United Nations Children's Fund), Qu Dongyu (Food and Agriculture Organization of the United Nations), David M Beasley (World Food Programme), and Tedros A Ghebreyesus (World Health Organization)
July 27, 2020
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31648-2/fulltext

> "The COVID-19 pandemic is undermining nutrition across the world, particularly in low-income and middle-income countries (LMICs). The worst consequences are borne by young children. **Some of the strategies to respond to COVID-19—including physical distancing, school closures, trade restrictions, and country lockdowns—are impacting food systems** by disrupting the production, transportation, and sale of nutritious, fresh, and affordable foods, forcing millions of families to rely on nutrient-poor alternatives [*emphasis added*]."

[70] ***A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID-19 mortality and related health outcomes***
The Lancet
Rabail Chaudhry, George Dranitsaris, Talha Mubashir, Justyna Bartoszko, and Sheila Riazi
July 21, 2020
https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30208-X/fulltext

> "**Background**: A country level exploratory analysis was conducted to assess the impact of timing and type of national health policy/actions undertaken towards COVID-19 mortality and related health outcomes.
>
> **3.4**. Factors affecting COVID-19 critical cases rates and mortality… Lastly, government actions such as border closures, full lockdowns, and a high rate of COVID-19 testing **were not associated with statistically significant reductions in the number of critical cases or overall mortality** [*emphasis added*]."

[71] ***The State of Food Security and Nutrition in the World***
United Nations
July 13, 2020
https://www.who.int/docs/default-source/nutritionlibrary/publications/state-food-security-nutrition-2020-inbrief-en.pdf?sfvrsn=65fbc6ed_4

> "A preliminary assessment suggests that the COVID-19 pandemic may add between **83 and 132 million people to the total number of undernourished** in the world in 2020 [*emphasis added*]…
>
> The nutritional status of the most vulnerable population groups is likely to deteriorate further due to the health and socio-economic impacts of COVID-19."

[72] ***Exploring inter-country coronavirus mortality***
PANDA (Pandemics – Data & Analytics)
Trevor Nell, Ian McGorian, and Nick Hudson
July 9, 2020
https://pandata.org/wp-content/uploads/2020/07/Exploring-inter-country-variation.pdf

> "**Abstract**. One of the most interesting features of the COVID-19 outbreak is the stark difference between mortality experience in different countries. No simple and plausible explanations that we are aware of have been advanced. Though various hypotheses have been put forward, some more hopeful than others, many display an element of confirmation bias in attempting to locate all differences in non-pharmaceutical intervention approaches.
>
> For each country put forward as an example, usually in some pairwise comparison and with an attendant single cause explanation, there are a host of countries that fail the expectation. We set out to model the disease with every expectation of failure. In choosing variables it was obvious from the outset that there would be contradictory outcomes in the real world. But there were certain variables that appeared to be reliable markers as they had surfaced in much of the media and pre-print papers. These included age, co-morbidity prevalence and the seemingly light population mortality rates in poorer countries than that in richer countries. Even the worst among developing nations—a clutch of countries in equatorial Latin America—have seen lighter overall population mortality than the developed world. Our aim therefore was not to develop the final answer, rather to seek common cause variables that would go some way to providing an explanation and stimulating discussion. There are some very obvious outliers in this theory, not the least of these being Japan.
>
> We test and find wanting the popular notions that lockdowns with their attendant social distancing and various other NPIs confer protection."

[73] ***Comment on Flaxman et al. (2020): The illusory effects of non-pharmaceutical interventions on COVID-19 in Europe***
Nature
Stefan Homburg and Christof Kuhbandner
June 17, 2020
https://advance.sagepub.com/articles/preprint/Comment_on_Flaxman_et_al_2020_The_illusory_effects_of_non-pharmaceutical_interventions_on_COVID-19_in_Europe/12479987/1

"In a recent article, Flaxman et al. allege that non-pharmaceutical interventions imposed by European countries saved millions of lives. We show that their methods involve circular reasoning. The purported effects are pure artefacts, which contradict the data. Moreover, we demonstrate that the United Kingdom's lockdown was both superfluous and ineffective."

[74] ***Millions in UK miss cancer screenings, tests and treatments due to Covid-19***
The Guardian
Denis Campbell
June 1, 2020
https://web.archive.org/web/20200724212540/https://amp.theguardian.com/society/2020/jun/01/millions-in-uk-miss-cancer-screenings-tests-and-treatments-due-to-covid-19

"Almost 2.5 million Britons have not been screened, tested or treated for cancer because the Covid-19 pandemic has led to 'enormous disruption' of NHS care for the disease, experts have warned.

More than 24,000 cases of cancer have gone undiagnosed as a result of the suspension of normal services while delays in treatment mean some people's disease is now inoperable, Cancer Research UK (CRUK) says."

[75] ***Projected Deaths of Despair from COVID-19***
The Well Being Trust
Stephen Petterson, John M. Westfall, and Benjamin F. Miller
May 8, 2020
http://psych-history.weill.cornell.edu/pdf/WBT_Deaths-of-Despair_COVID-19-FINAL-FINAL.pdf

"**Executive Summary**: More Americans could lose their lives to deaths of despair, deaths due to drug, alcohol, and suicide, if we do not do something immediately. Deaths of despair have been on the rise for the last decade, and in the context of COVID-19, deaths of despair should be seen as the epidemic within the pandemic. The goal of this report is to predict what deaths of despair we might see based on three assumptions during COVID-19: economic recovery, relationship between deaths of despair and unemployment, and geography. Across nine different scenarios, additional deaths of despair range from 27,644 (quick recovery, smallest impact of unemployment on deaths of despair) to 154,037 (slow recovery, greatest impact of unemployment on deaths of despair), with somewhere in the middle being around 68,000."

[76] ***Coronavirus could push half a billion more people into poverty globally, UN warns***
CNBC
Vicky McKeever
April 9. 2020
https://www.cnbc.com/2020/04/09/coronavirus-could-push-half-a-billion-people-into-poverty-globally.html

"The coronavirus pandemic could result in between 420 million and 580 million more people, or 8% of the global population, living in poverty, a study by the United Nations University has found.

Researchers based their calculations on the most extreme scenario of a 20% decline in income or consumption around the world. This looked at people falling below the three international poverty lines of living on less than $1.90, $3.20 or $5.50 a day.

Higher estimates could mean that half of the overall global population of 7.8 billion people could be living in poverty by the end of the pandemic."

[77] ***China is being "quite transparent," says NIH head***
CNN
Ellie Kaufman
January 24, 2020
https://www.cnn.com/asia/live-news/coronavirus-outbreak-hnk-intl-01-24-20/h_0858158c176ba286f23a8628c3b9b925

"Fauci said that China's decision to shut down travel may not have a huge impact on containing the spread... 'That's something that I don't think we could possibly do in the United States, I can't imagine shutting down New York or Los Angeles, but the judgement on the part of the Chinese health authorities is that given the fact that it's spreading throughout the provinces... it's their judgement that this is something that in fact is going to help in containing it. Whether or not it does or does not is really open to question because historically when you shut things down **it doesn't have a major effect** [*emphasis added*]."

[78] ***Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza***
World Health Organization (WHO)
2019
https://apps.who.int/iris/bitstream/handle/10665/329438/9789241516839-eng.pdf

Table 4. Summary of recommendations for each NPI [*non-pharmaceutical intervention*]

MEASURES	RECOMMENDATIONS	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION	WHEN TO APPLY
Isolation of sick individuals	Voluntary isolation at home of sick individuals with uncomplicated illness is recommended during all influenza epidemics and pandemics, with the exception of the individuals who need to seek medical attention. The duration of isolation depends on the severity of illness (usually 5–7 days) until major symptoms disappear.	Very low (effective)	Recommended	At all times
Quarantine of exposed individuals	Home quarantine of exposed individuals to reduce transmission is not recommended because there is no obvious rationale for this measure, and there would be considerable difficulties in implementing it.	Very low (variable effectiveness)	Not recommended	N/A

[79] ***Preparedness for a High-Impact Respiratory Pathogen Pandemic***
Johns Hopkins Center for Health Security
September 2019
Jennifer B. Nuzzo, Lucia Mullen, *et al.*
https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2019/190918-GMPBreport-respiratorypathogen.pdf

"During an emergency, it should be expected that implementation of some NPIs [*non-pharmaceutical interventions*], such as travel restrictions and quarantine, might be pursued for social or political purposes by political leaders, **rather than pursued because of public health evidence** [*emphasis added*]…

In the context of a high-impact respiratory pathogen, **quarantine may be the least likely NPI to be effective in controlling the spread** due to high transmissibility [*emphasis added*]. To implement effective quarantine measures, it would need to be possible to accurately evaluate an individual's exposure, which would be difficult to do for a respiratory pathogen because of the ease of widespread transmission from infected individuals. Quarantine measures will be least effective for pathogens that are highly transmissible, have short incubation periods, and spread through true airborne mechanisms, as opposed to droplets. As with travel restrictions, quarantine appears to delay the introduction of highly transmissible diseases but not prevent their spread entirely. Quarantine measures also appear more effective with pathogens that had a longer incubation period, such as measles, compared to those with shorter incubation periods, such as influenza. Experiences with quarantine during the West Africa Ebola epidemic highlight the added difficulty of implementing such measures on a large scale, which would only be more difficult in the case of a highly transmissible respiratory disease."

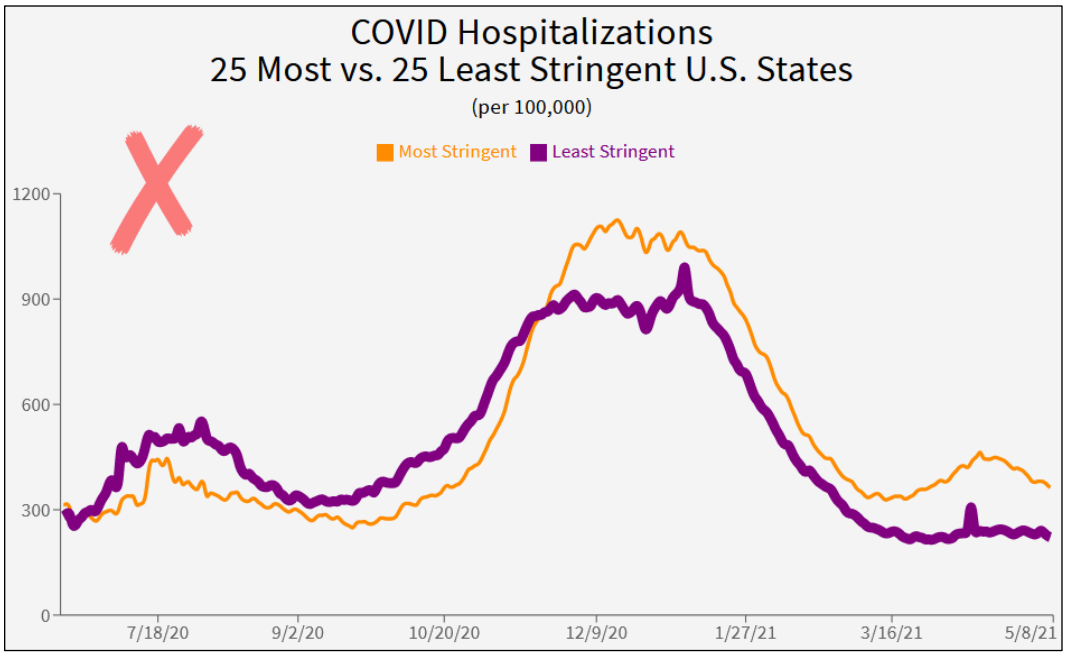
Masks and Mask Mandates

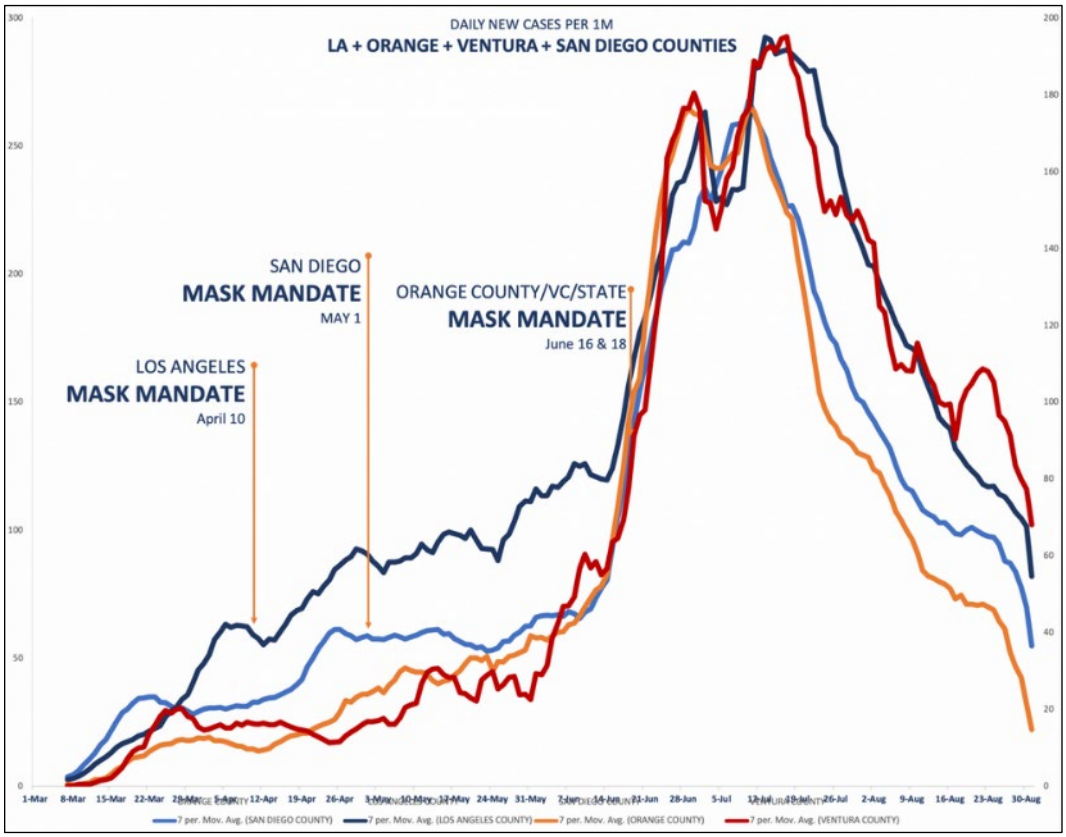
[80] ***#Are Face Masks Effective? The Evidence.***
Swiss Policy Research
Published July 2020, updated February 2023
A review of existing studies examining the effectiveness of face masks, the development of COVID-19 cases after mask mandates, and the health risks associated with face masks.
https://swprs.org/face-masks-evidence/

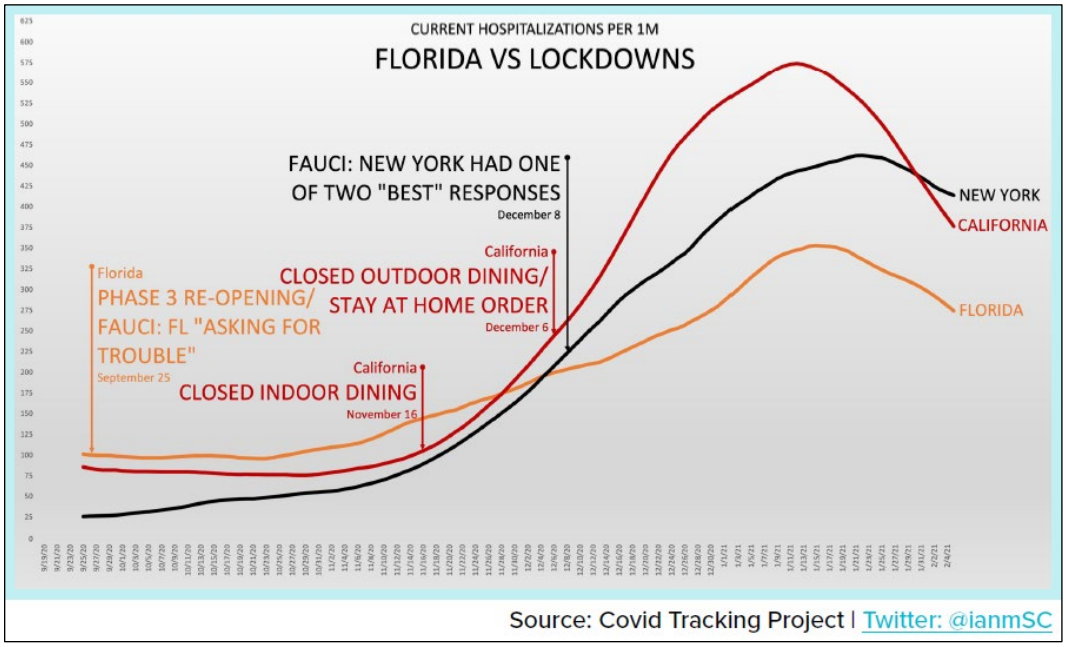
> "**Conclusion**: Face masks in the general population might be effective, at least in some circumstances, but there is currently little to no evidence supporting this proposition. If the coronavirus is indeed transmitted via indoor aerosols, face masks are unlikely to be protective. Thus, health authorities should not assume or suggest that face masks will reduce the rate or risk of infection."

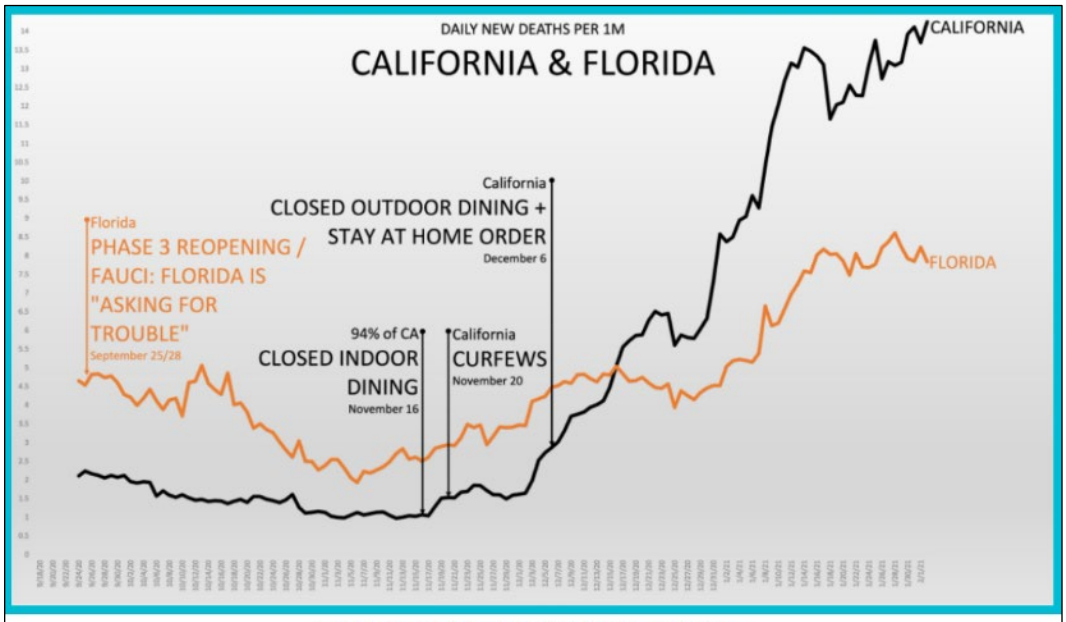
[81] **Mask charts**
A collection of charts from a wide range of jurisdictions demonstrating the lack of correlation (and, thus, causation) between governmental imposition of mask mandates and case, hospitalization, and death rates. (Source data: The COVID Tracking Project and Our World in Data)
https://rationalground.com/mask-charts/
https://rationalground.com/more-mask-charts/
https://twitter.com/yinonw/status/1321177359601393664
https://tomwoods.com/covid/
COVID-Charts Quiz: https://www.covidchartsquiz.com/

Mask-chart Examples:

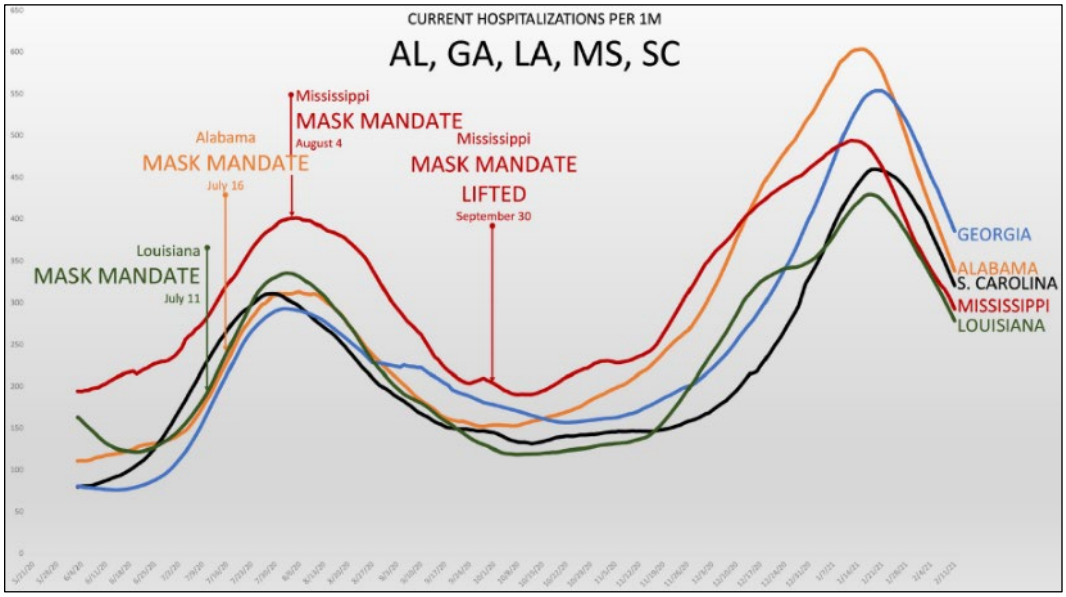


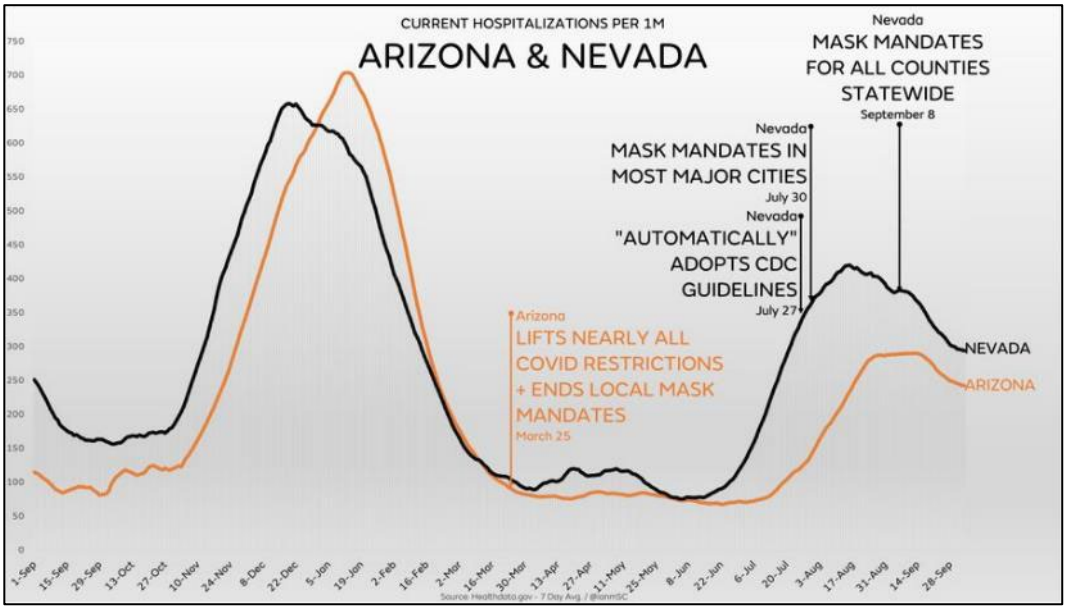

DAILY NEW CASES PER 1M
LA + ORANGE + VENTURA + SAN DIEGO COUNTIES
SAN DIEGO
MASK MANDATE
MAY 1
ORANGE COUNTY/VC/STATE
MASK MANDATE
June 16 & 18
LOS ANGELES
MASK MANDATE
April 10
7 per. Mov. Avg. (SAN DIEGO COUNTY)
7 per. Mov. Avg. (LOS ANGELES COUNTY)
7 per. Mov. Avg. (ORANGE COUNTY)
7 per. Mov. Avg. (VENTURA COUNTY)

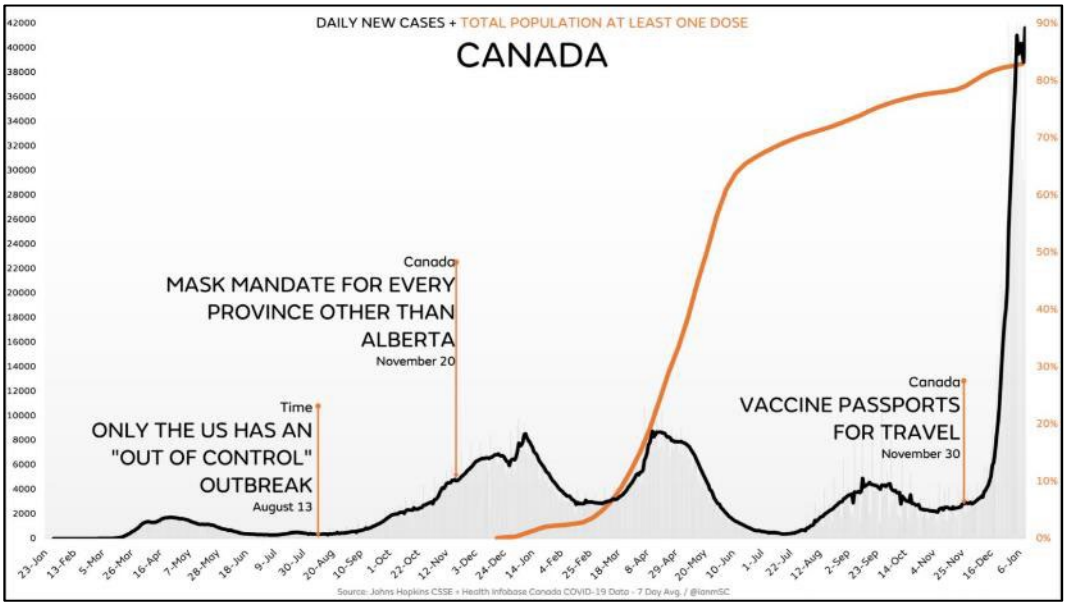

CURRENT HOSPITALIZATIONS PER 1M
FLORIDA VS LOCKDOWNS
FAUCI: NEW YORK HAD ONE OF TWO "BEST" RESPONSES
December 8
California
CLOSED OUTDOOR DINING/ STAY AT HOME ORDER
December 6
Florida
PHASE 3 RE-OPENING/ FAUCI: FL "ASKING FOR TROUBLE"
September 25
California
CLOSED INDOOR DINING
November 16
NEW YORK
CALIFORNIA
FLORIDA
Source: Covid Tracking Project | Twitter: @ianmSC

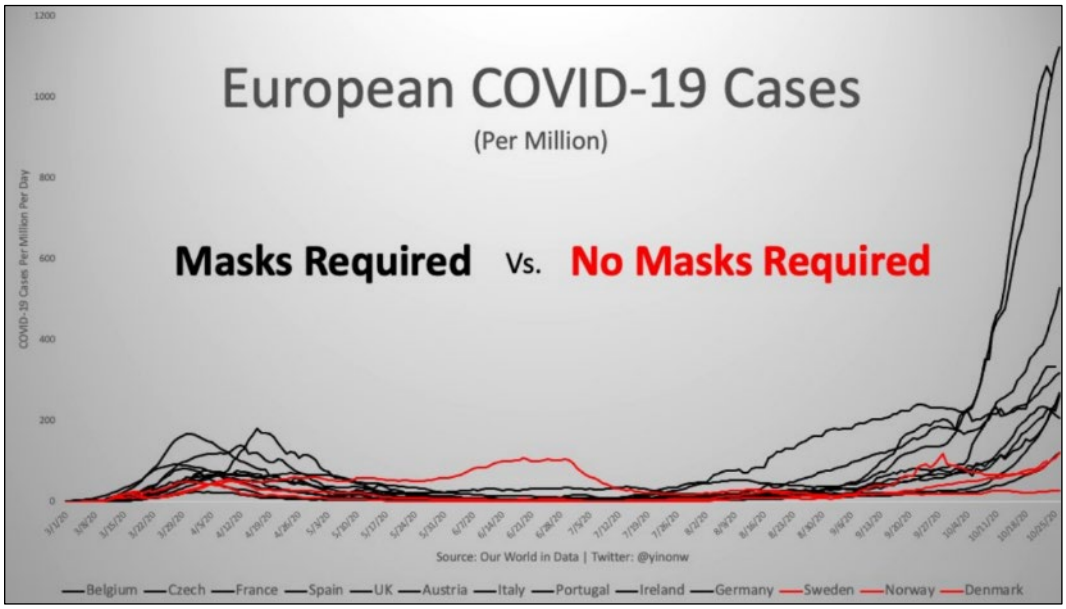


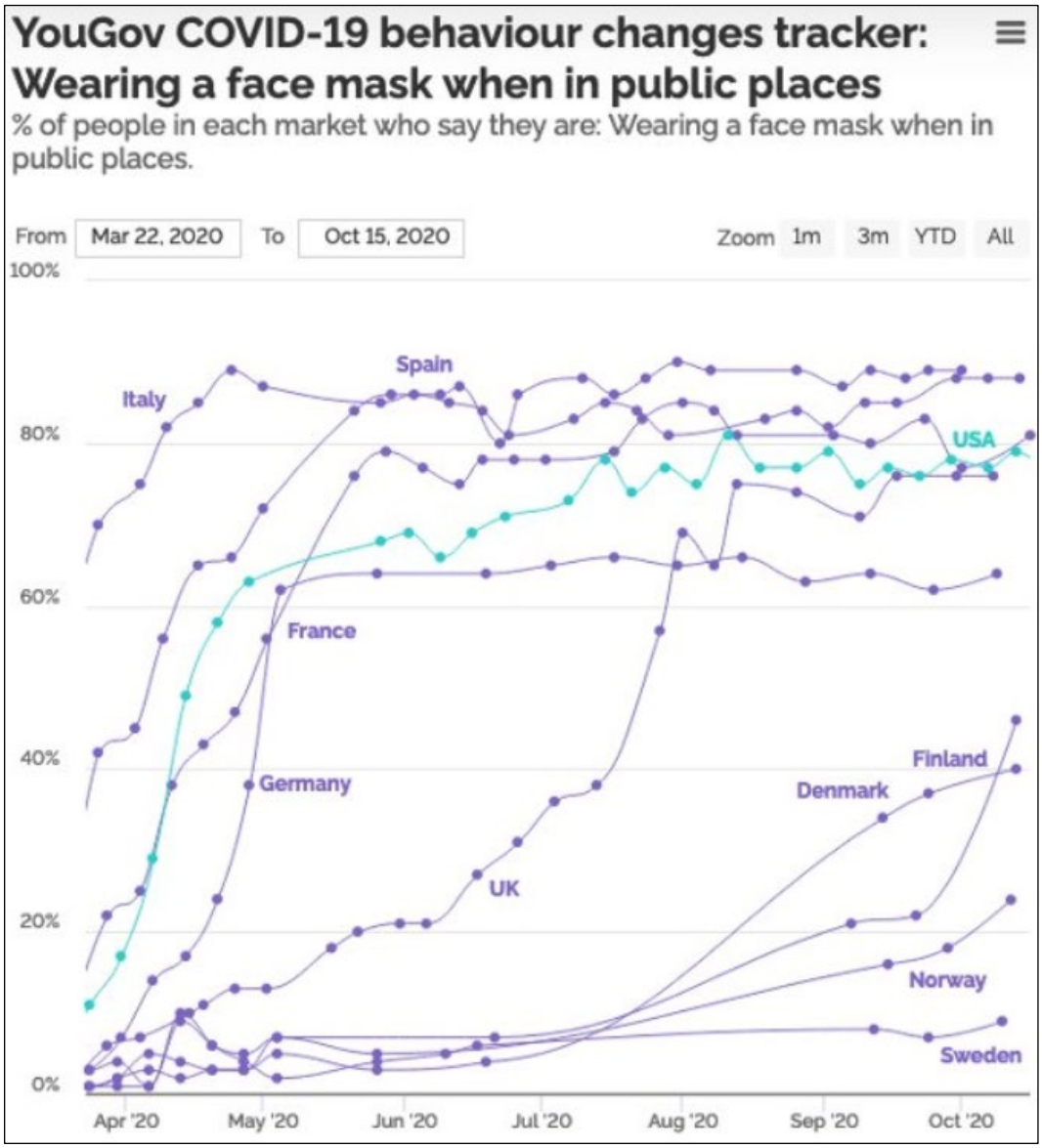
Source: Covid Tracking Project | Twitter: @ianmSC



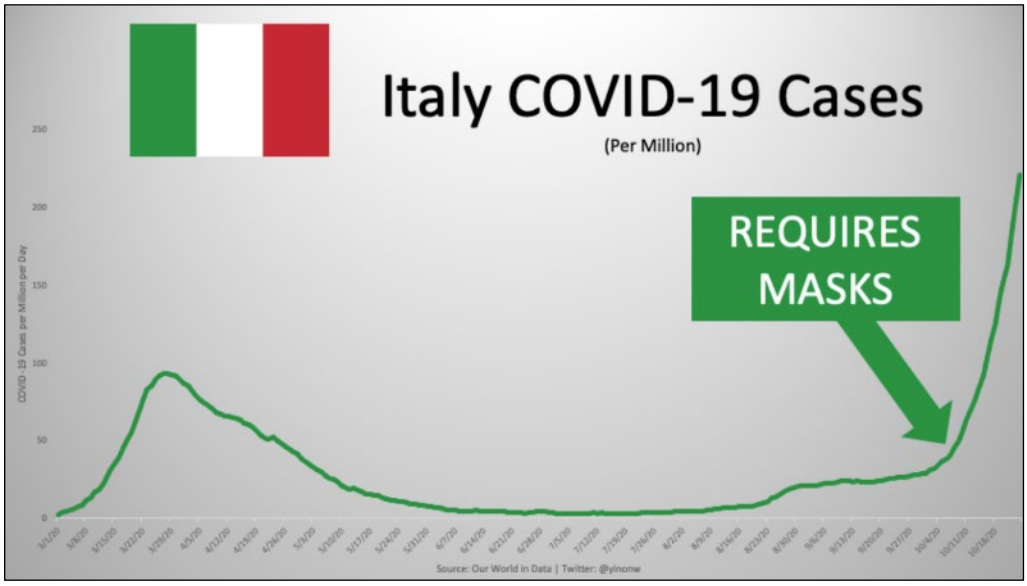

CURRENT HOSPITALIZATIONS PER 1M
ARIZONA & NEVADA
Nevada
MASK MANDATES
FOR ALL COUNTIES
STATEWIDE
September 8
Nevada
MASK MANDATES IN
MOST MAJOR CITIES
July 30
Nevada
"AUTOMATICALLY"
ADOPTS CDC
GUIDELINES
July 27
Arizona
LIFTS NEARLY ALL
COVID RESTRICTIONS
+ ENDS LOCAL MASK
MANDATES
March 25
NEVADA
ARIZONA


DAILY NEW CASES + TOTAL POPULATION AT LEAST ONE DOSE
CANADA
Canada
MASK MANDATE FOR EVERY
PROVINCE OTHER THAN
ALBERTA
November 20
Time
ONLY THE US HAS AN
"OUT OF CONTROL"
OUTBREAK
August 13
Canada
VACCINE PASSPORTS
FOR TRAVEL
November 30

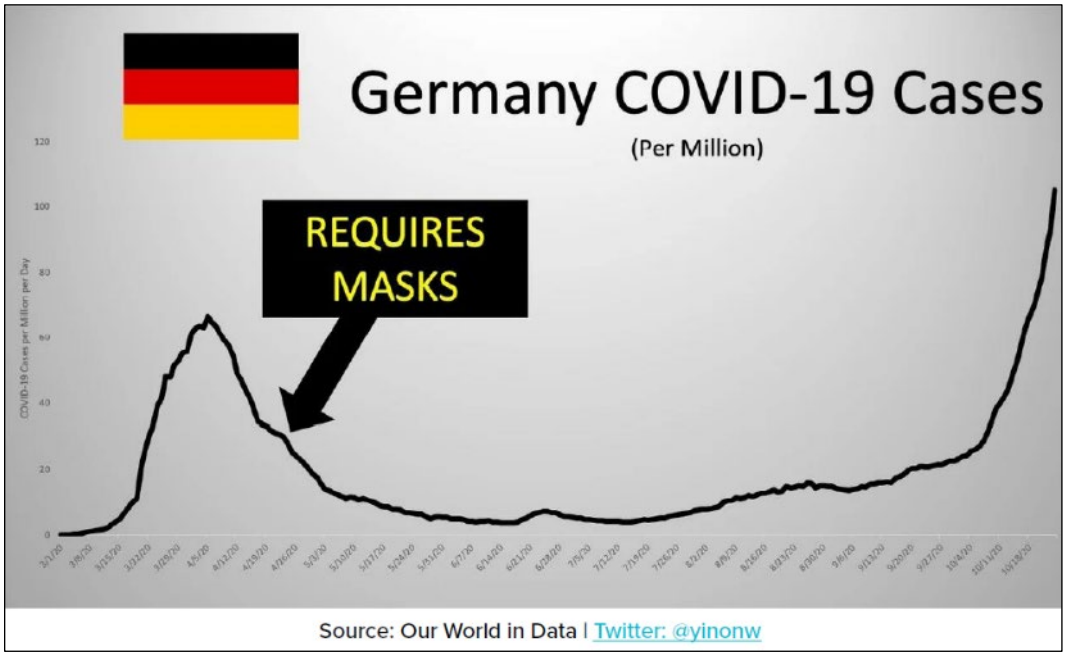

European COVID-19 Cases
(Per Million)
Masks Required Vs. No Masks Required
COVID-19 Cases Per Million Per Day
1200
1000
800
600
400
200
0
Source: Our World in Data | Twitter: @yinonw
Belgium Czech France Spain UK Austria Italy Portugal Ireland Germany Sweden Norway Denmark

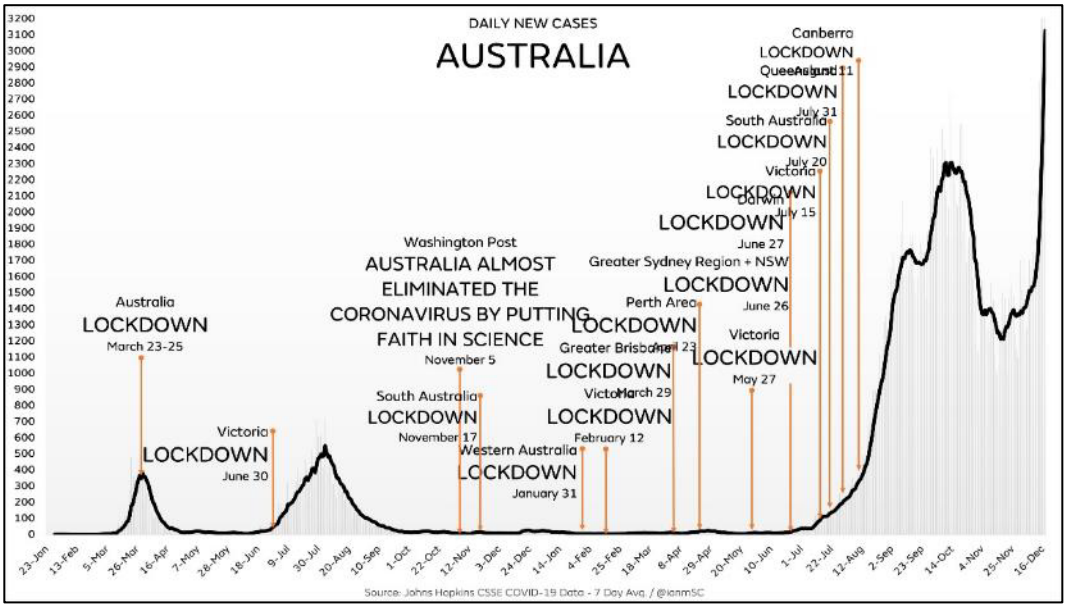

YouGov COVID-19 behaviour changes tracker:
Wearing a face mask when in public places
% of people in each market who say they are: Wearing a face mask when in public places.
From Mar 22, 2020
To Oct 15, 2020
Zoom 1m 3m YTD All
100%
80%
60%
40%
20%
0%
Spain
Italy
USA
France
Germany
Finland
Denmark
UK
Norway
Sweden
Apr '20
May '20
Jun '20
Jul '20
Aug '20
Sep '20
Oct '20

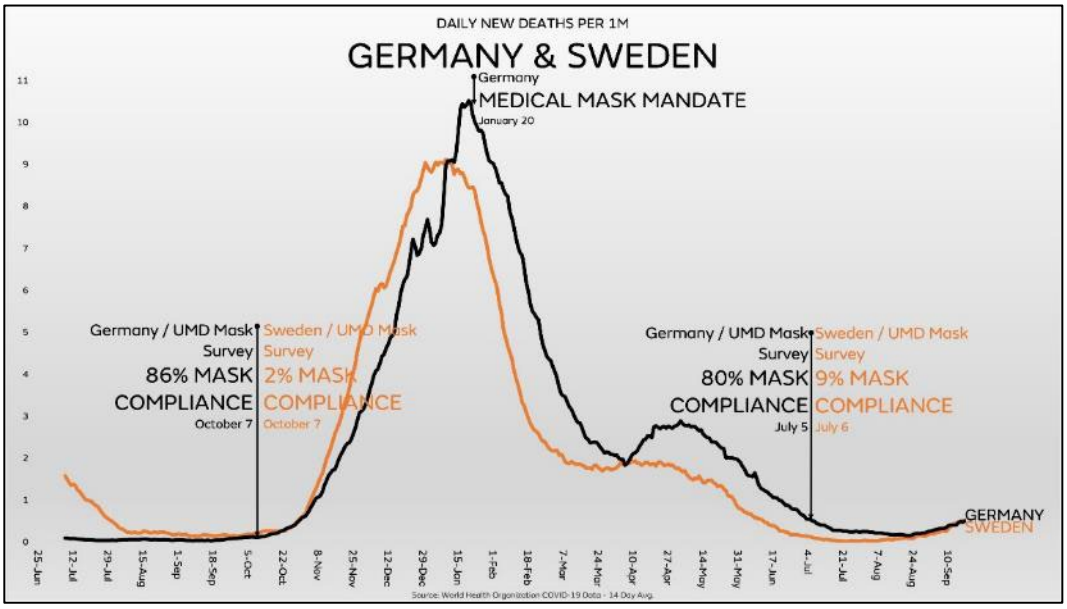
UK COVID-19 Cases
(Per Million)
REQUIRES MASKS
COVID-19 Cases per Million per Day
Source: Our World in Data | Twitter: @yinonw

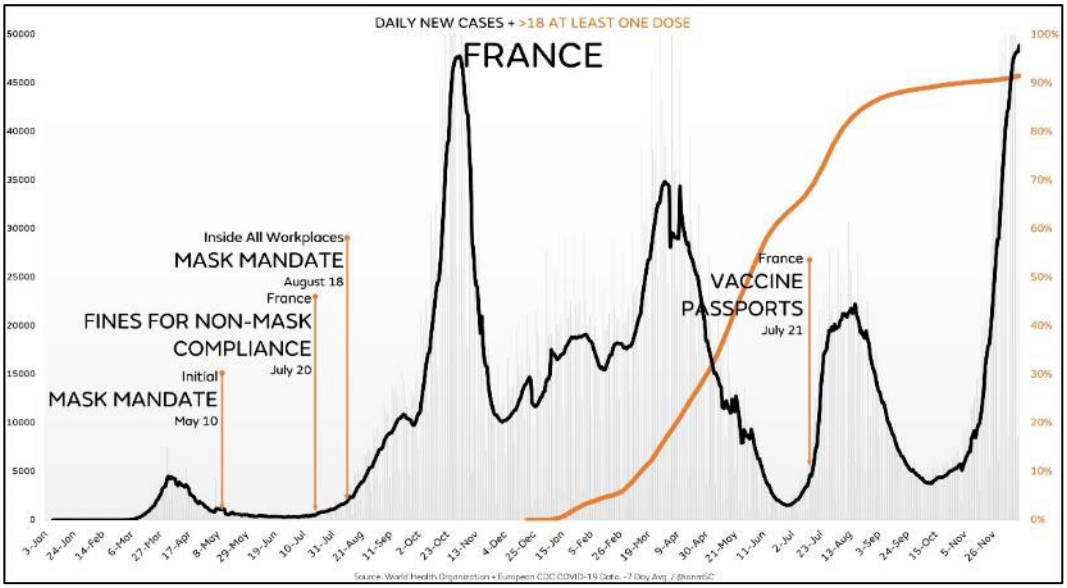

Italy COVID-19 Cases
(Per Million)
REQUIRES MASKS
COVID-19 Cases per Million per Day
Source: Our World in Data | Twitter: @yinonw

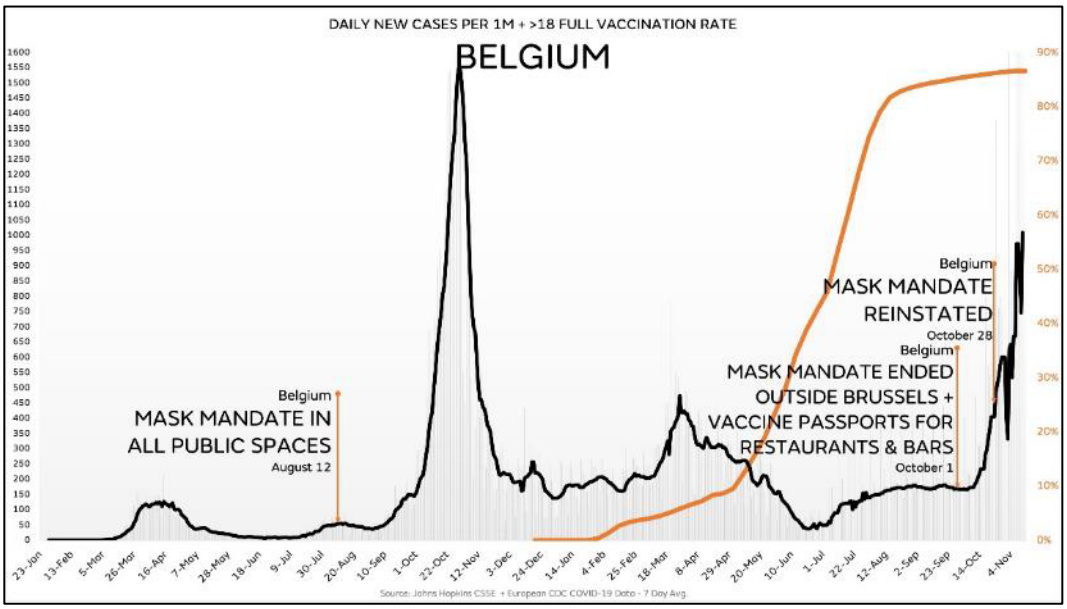
Spain COVID-19 Cases
(Per Million)
REQUIRES MASKS
COVID-19 Cases per Million per Day
Source: Our World in Data | Twitter: @yinonw

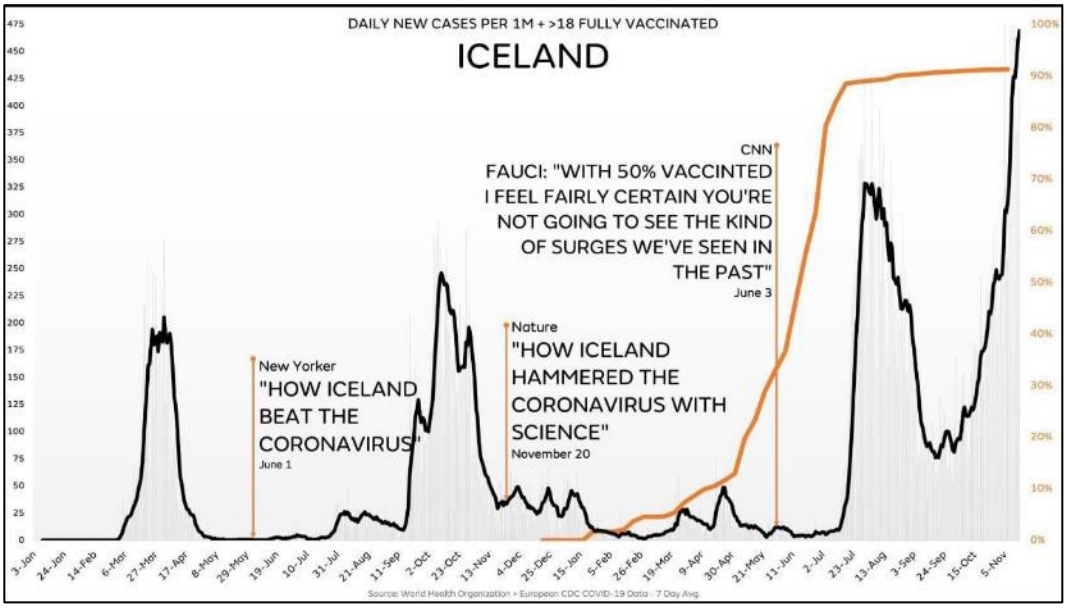

Germany COVID-19 Cases
(Per Million)
REQUIRES MASKS
COVID-19 Cases per Million per Day
Source: Our World in Data | Twitter: @yinonw

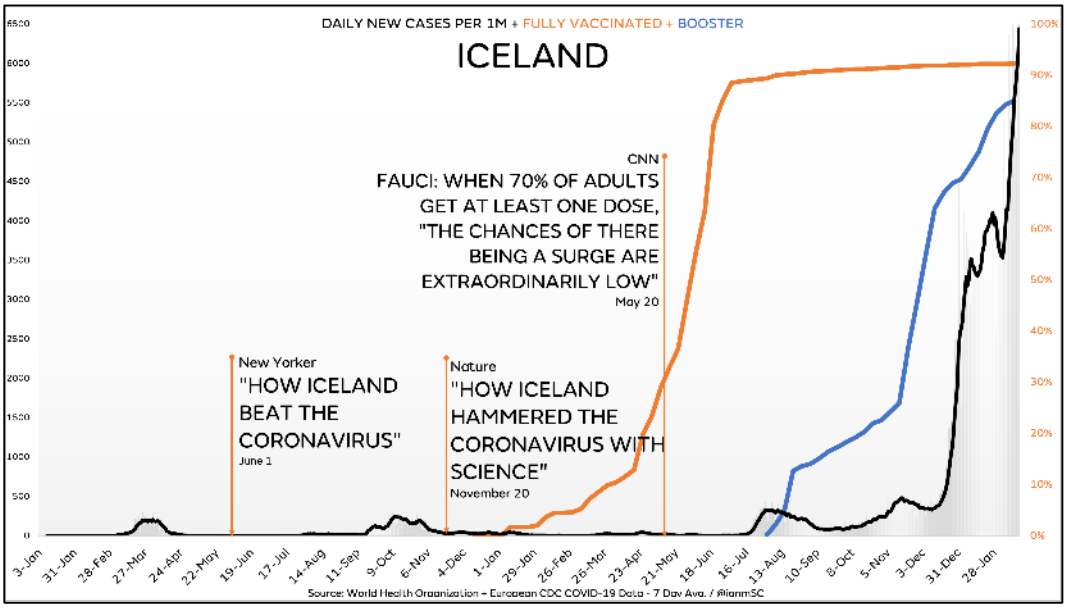

DAILY NEW CASES
AUSTRALIA
Australia
LOCKDOWN
March 23-25
Victoria
LOCKDOWN
June 30
Washington Post
AUSTRALIA ALMOST
ELIMINATED THE
CORONAVIRUS BY PUTTING
FAITH IN SCIENCE
November 5
South Australia
LOCKDOWN
November 17
Western Australia
LOCKDOWN
January 31
LOCKDOWN
February 12
Perth Area
LOCKDOWN
March 29
Greater Sydney Region + NSW
LOCKDOWN
June 26
Victoria
LOCKDOWN
May 27
Darwin
LOCKDOWN
June 27
Victoria
LOCKDOWN
July 15
South Australia
LOCKDOWN
July 20
LOCKDOWN
July 31
Canberra
LOCKDOWN
August 11
Source: Johns Hopkins CSSE COVID-19 Data - 7 Day Avg. / @jannSC

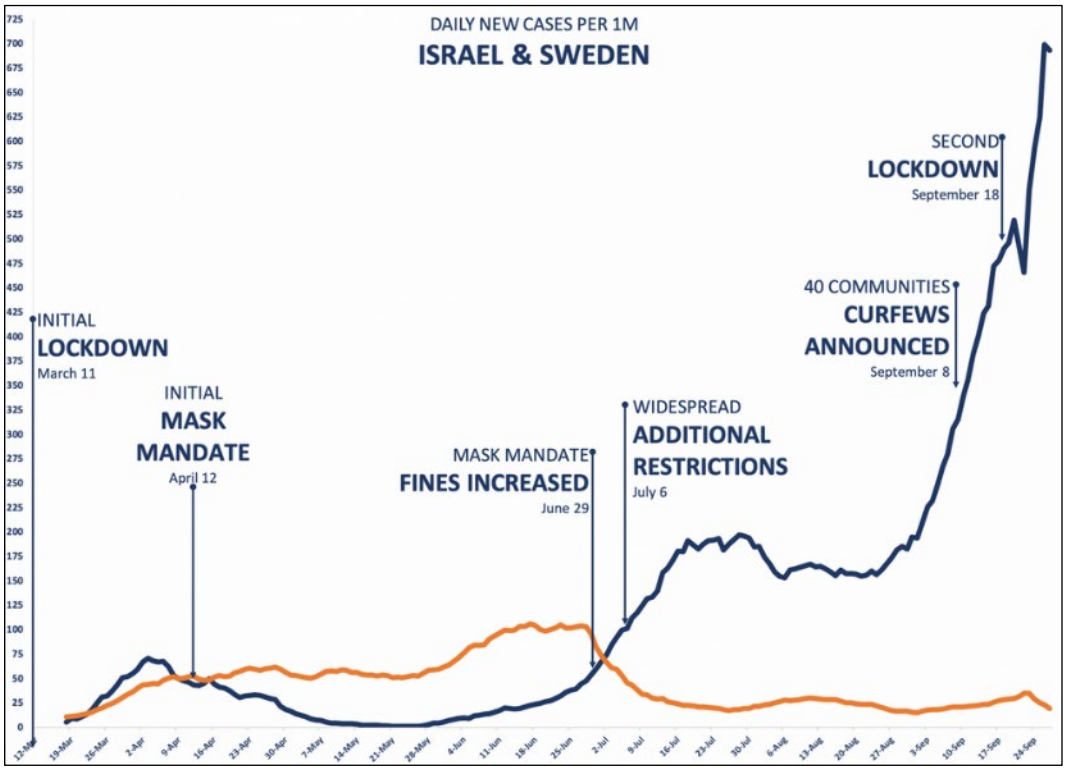

DAILY NEW DEATHS PER 1M
GERMANY & SWEDEN
Germany
MEDICAL MASK MANDATE
January 20
Germany / UMD Mask Survey
86% MASK COMPLIANCE
October 7
Sweden / UMD Mask Survey
2% MASK COMPLIANCE
October 7
Germany / UMD Mask Survey
80% MASK COMPLIANCE
July 5
Sweden / UMD Mask Survey
9% MASK COMPLIANCE
July 6
GERMANY
SWEDEN
Source: World Health Organization COVID-19 Data - 14 Day Avg.

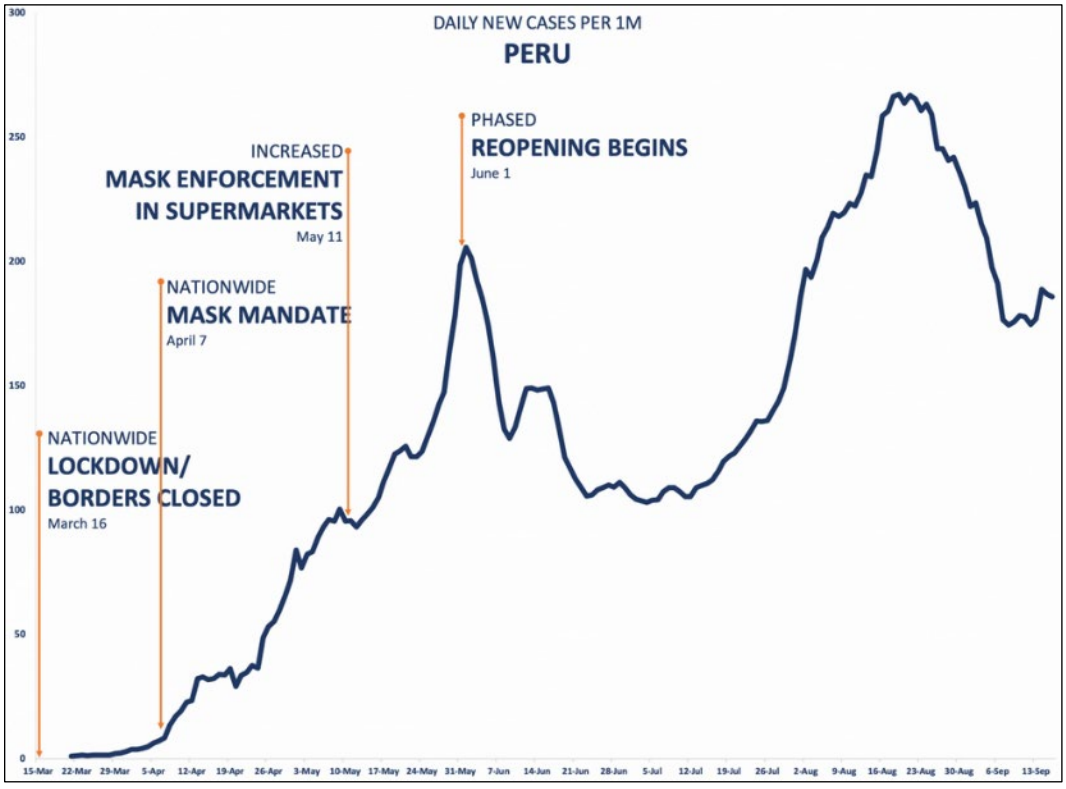

DAILY NEW CASES + >18 AT LEAST ONE DOSE
FRANCE
Inside All Workplaces
MASK MANDATE
August 18
France
FINES FOR NON-MASK
COMPLIANCE
July 20
Initial
MASK MANDATE
May 10
France
VACCINE
PASSPORTS
July 21


DAILY NEW CASES PER 1M + >18 FULL VACCINATION RATE
BELGIUM
Belgium
MASK MANDATE IN
ALL PUBLIC SPACES
August 12
Belgium
MASK MANDATE
REINSTATED
October 28
Belgium
MASK MANDATE ENDED
OUTSIDE BRUSSELS +
VACCINE PASSPORTS FOR
RESTAURANTS & BARS
October 1


DAILY NEW CASES PER 1M + >18 FULLY VACCINATED
ICELAND
CNN
FAUCI: "WITH 50% VACCINTED I FEEL FAIRLY CERTAIN YOU'RE NOT GOING TO SEE THE KIND OF SURGES WE'VE SEEN IN THE PAST"
June 3
Nature
"HOW ICELAND HAMMERED THE CORONAVIRUS WITH SCIENCE"
November 20
New Yorker
"HOW ICELAND BEAT THE CORONAVIRUS"
June 1
Source: World Health Organization + European CDC COVID-19 Data - 7 Day Avg.


DAILY NEW CASES PER 1M + FULLY VACCINATED + BOOSTER
ICELAND
CNN
FAUCI: WHEN 70% OF ADULTS GET AT LEAST ONE DOSE, "THE CHANCES OF THERE BEING A SURGE ARE EXTRAORDINARILY LOW"
May 20
Nature
"HOW ICELAND HAMMERED THE CORONAVIRUS WITH SCIENCE"
November 20
New Yorker
"HOW ICELAND BEAT THE CORONAVIRUS"
June 1
Source: World Health Organization – European CDC COVID-19 Data - 7 Day Avg. / @IanmSC


DAILY NEW CASES PER 1M
ISRAEL & SWEDEN
INITIAL
LOCKDOWN
March 11
INITIAL
MASK
MANDATE
April 12
MASK MANDATE
FINES INCREASED
June 29
WIDESPREAD
ADDITIONAL
RESTRICTIONS
July 6
40 COMMUNITIES
CURFEWS
ANNOUNCED
September 8
SECOND
LOCKDOWN
September 18


DAILY NEW CASES PER 1M
PERU
NATIONWIDE
LOCKDOWN/
BORDERS CLOSED
March 16
NATIONWIDE
MASK MANDATE
April 7
INCREASED
MASK ENFORCEMENT
IN SUPERMARKETS
May 11
PHASED
REOPENING BEGINS
June 1

Note: The citations below are presented in reverse, chronological order.

[82] **ADDED since 2/8/2022**
Video (1m): *Biden COVID Czar admits the Truth about Masks*
Philadelphia Inquirer interview with Ashish Jha, White House COVID-19 Response Coordinator
December 22, 2022
https://rumble.com/v21wmde-biden-covid-czar-finally-admits-the-truth-about-masks.html

> "Indoor air quality has just not gotten the level of attention it deserves. You know, most experts believe that if we make some basic investments in indoor air quality, we can reduce all respiratory infections by 30, 60, or even 80 percent.
>
> I mean the notion that you could cut respiratory infections, there's no study in the world that shows that masks work that well. So you're never going to get the kind of benefit from mandatory, year-round masking as you would from making substantial improvements in indoor air quality."

[83] **ADDED since 2/8/2022**
Lack of correlation between school mask mandates and paediatric COVID-19 cases in a large cohort
Journal of Infection
Ambarish Chandra and Tracy Beth Høeg
November 29, 2022
https://www.sciencedirect.com/science/article/pii/S0163445322005503

> "**Objectives**: To expand upon an observational study published by the Centers for Disease Control (CDC) showing an association between school mask mandates and lower pediatric COVID-19 cases. We examine whether this association persists in a larger, nationally representative dataset over a longer period.

Method: We replicated the CDC study and extended it to more districts and a longer period, employing seven times as much data. We examined the relationship between mask mandates and per-capita pediatric cases, using multiple regression to control for observed differences.

Results: We successfully replicated the original result using 565 counties; non-masking counties had around 30 additional daily cases per 100,000 children after two weeks of schools reopening. However, after nine weeks, cases per 100,000 were **18.3 in counties with mandates** compared to **15.8 in those without them** ($p = 0.12$). In a larger sample of 1832 counties, between weeks 2 and 9, cases per 100,000 fell by 38.2 and 37.9 in counties with and without mask requirements, respectively ($p = 0.93$).

Conclusions: The association between school mask mandates and cases did not persist in the extended sample. Observational studies of interventions are **prone to multiple biases** and provide insufficient evidence for recommending mask mandates."

[84] **ADDED since 2/8/2022**

Inhaled CO2 Concentration While Wearing Face Masks: A Pilot Study Using Capnography

Environmental Health Insights (SAGE Journals) — University of Ferrara, Italy

Cecilia Acuti Martellucci, Maria Elena Flacco, *et al*.

September 15, 2022

https://journals.sagepub.com/doi/10.1177/11786302221123573

"**Introduction**: Surgical masks and respirators are assumed to reduce the spread of SARS-CoV-2,2 and are believed to decrease the incidence of other airborne infections. On the other hand, a prolonged mask use has been associated with higher viral loads and more severe symptoms in infected people (possibly due to the re-inhalation of viral particles trapped in the mask), with skin disorders due to pathogens contamination, a higher likelihood of frequent cough, sputum production, dyspnea, and panic attacks, with delayed cognitive development in infants, and with a substantial rise of inhaled carbon dioxide (CO_2), which in turn may cause other symptoms.

Few studies, however, directly assessed CO_2 in air inhaled while wearing masks in the general population…

With the present study, we aimed at expanding the evidence about the potential inhalation of excess CO_2 as a consequence of wearing surgical masks or FFP2 respirators, among adults, children, and the elderly. Therefore, we used a professional real-time capnograph, with water-removal tubing, in order to assess the inhaled air CO_2 concentration in a sample of healthy individuals wearing different types of masks…

Data analysis: The primary outcome was the mean inhaled air CO_2 concentration when wearing masks. The secondary outcome was the proportion of individuals with inhaled air CO_2 concentration exceeding 5000 ppm, which is the long-term (8-hours average) threshold indicated as Permissible Exposure Limit by the United States Department of Labor Occupational Safety and Health Administration (OSHA), and as Indicative Occupational Exposure Limit by the European Agency for Safety and Health at Work (EU-OSHA)…

Outcomes: The mean inhaled air CO_2 without masks was 460 ± 20 ppm. While wearing the surgical mask, the **mean CO_2 was 5087 ± 1579 ppm** (95% confidence interval 4828-5346 ppm), and **exceeded 5000 ppm in 41.1%** (33.0%-49.5%) **of the measurements**. While wearing the FFP2 respirator, the average CO_2 was 9653 ± 2874 ppm (9183-10 123 ppm), and

98.6% (95.2%-99.8%) of the participants showed values higher than 5000 ppm (Table 1). **Among the minors**, **the mean CO2 concentration when wearing surgical masks was 7091 ± 2491 ppm** (6039-8144 ppm), and was considerably higher than among the adults (4835 ± 869 ppm; P < .01), or the elderly (4379 ± 978 ppm; P < .001). A similar difference by age class was observed also for the FFP2 respirators (Table 2).

Note: According to this 2016 article published by Occupational Safety and Health (OSH), a CO2 level exceeding 5,000 ppm "indicates unusual air conditions where high levels of other gases also could be present. Toxicity or oxygen deprivation could occur":

https://ohsonline.com/Articles/2016/04/01/Carbon-Dioxide-Detection-and-Indoor-Air-Quality-Control.aspx?Page=2

[85] **ADDED since 2/8/2022**

Bacterial and fungal isolation from face masks under the COVID-19 pandemic

Nature Scientific Reports — Kindai University Faculty of Medicine, Japan
Ah-Mee Park, Sundar Khadka, *et al*.
July 18, 2022
https://www.nature.com/articles/s41598-022-15409-x

"**Abstract**: The COVID-19 pandemic has led people to wear face masks daily in public. Although the effectiveness of face masks against viral transmission has been extensively studied, there have been few reports on potential hygiene issues due to bacteria and fungi attached to the face masks. We aimed to (1) quantify and identify the bacteria and fungi attaching to the masks, and (2) investigate whether the mask-attached microbes could be associated with the types and usage of the masks and individual lifestyles. We surveyed 109 volunteers on their mask usage and lifestyles, and cultured bacteria and fungi from either the face-side or outer-side of their masks. The bacterial colony numbers were greater on the face-side than the outer-side; the fungal colony numbers were fewer on the face-side than the outer-side. A longer mask usage significantly increased the fungal colony numbers but not the bacterial colony numbers. Although most identified microbes were non-pathogenic in humans; Staphylococcus epidermidis, Staphylococcus aureus, and Cladosporium, **we found several pathogenic microbes**; Bacillus cereus, Staphylococcus saprophyticus, Aspergillus, and Microsporum. We also found no associations of mask-attached microbes with the transportation methods or gargling. We propose that **immunocompromised people should avoid repeated use of masks** to prevent microbial infection."

[86] **ADDED since 2/8/2022**

Association between School Mask Mandates and SARS-CoV-2 Student Infections: Evidence from a Natural Experiment of Neighboring K-12 Districts in North Dakota

University of Southern California
Neeraj, Sood, Shannon Heick, Josh Stevenson, and Tracy Høeg
July 1, 2022
https://www.researchsquare.com/article/rs-1773983/v1

"**Abstract**: There is still considerable debate about whether mask mandates in the K-12 schools limit transmission of SARS-CoV-2 in children attending school. Randomized data about the effectiveness of mask mandates in children is still entirely lacking. Our study took advantage of a unique natural experiment of two adjacent K-12 school districts in Fargo, North Dakota, one which had a mask mandate and one which did not in the fall of the 2021-2022

academic year. In the winter, both districts adopted a masks-optional policy allowing for a partial crossover study design. We observed **no significant difference** between student case rates while the districts had differing masking policies (IRR 0.99; 95% CI: 0.92 to 1.07) nor while they had the same mask policies (IRR 1.04; 95% CI: 0.92 to 1.16). The IRRs across the two periods were also not significantly different (p = 0.40). Our findings contribute to a growing body of literature which suggests **school-based mask mandates have limited to no impact on the case rates of COVID-19 among K-12 students**."

[87] **ADDED since 2/8/2022**

Carbon dioxide rises beyond acceptable safety levels in children under nose and mouth covering: Results of an experimental measurement study in healthy children

Environmental Research
Harald Walach, Helmut Traindl, *et al*.
May 31, 2022
https://www.sciencedirect.com/science/article/pii/S001393512200891X

"**Abstract**: Nose and mouth covering (NMC) has been made compulsory for children in many countries during the Covid-19 pandemic. We wanted to determine the average CO2 levels in inhaled air with NMC in children between age 6 and 17... We measured **13,100 ppm** (SD 380) under surgical mask and **13,900 ppm** (SD 370) under FFP2 mask in inhaled air... Wearing of NMC (surgical masks or FFP2- -masks) raises CO2 content in inhaled air quickly to a **very high level** in healthy children in a seated resting position that **might be hazardous to children's health**…

Introduction: … **Maximum concentration** at the work place for healthy adults during 8 h of work and 40 h per week as a time-weighted average is considered **0.5 vol% or 5,000 ppm**. This limit is accepted in many countries, for instance in Germany (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung, 2021) or in the United States (Centers for Disease Control and Prevention (CDC), 2019)."

[88] **ADDED since 2/8/2022**

Revisiting Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1—October 20 2021

The Lancet — University of Toronto
Ambarish Chandra & Tracy Beth Høeg
May 25, 2022
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4118566

"**Background**: … The Centers for Disease Control in the U.S. have released multiple observational studies suggesting that school mask mandates significantly reduce case rates. However, there have also been numerous additional US and international observational studies finding no significant effect of school mask mandates on pediatric cases.

Methods: Our study replicates a highly cited CDC study showing a negative association between school mask mandates and pediatric SARS-CoV-2 cases. We then extend the study using a larger sample of districts and a longer time interval, employing almost six times as much data as the original study. We examine the relationship between mask mandates and per-capita pediatric cases, using multiple regression to control for differences across school districts.

Findings: Replicating the CDC study shows similar results; however, incorporating a larger sample and longer period showed **no significant relationship** between mask mandates and case rates. These results persisted when using regression methods to control for differences across districts.

Interpretation: … We failed to establish a relationship between school masking and pediatric cases using the same methods but a larger, more nationally diverse population over a longer interval. Our study demonstrates that observational studies of interventions with small to moderate effect sizes are prone to bias caused by selection and omitted variables. Randomized studies can more reliably inform public health policy."

[89] **ADDED since 2/8/2022**

Correlation Between Mask Compliance and COVID-19 Outcomes in Europe

Beny Spira, Ph.D., M.Sc.

April 19, 2022

https://www.cureus.com/articles/93826-correlation-between-mask-compliance-and-covid-19-outcomes-in-europe

"**Study design**: This analysis aimed to verify whether mask usage was correlated with COVID-19 morbidity and mortality. Daily data on COVID-19 cases and deaths and on mask usage were obtained for all European countries…

Results: … The findings presented in this short communication suggest that countries with high levels of mask compliance **did not** perform better than those with low mask usage in the six-month period that encompassed the second European wave of COVID-19…

Conclusions: … [T]he lack of negative correlations between mask usage and COVID-19 cases and deaths suggest that the widespread use of masks at a time when an effective intervention was most needed, i.e., during the strong 2020-2021 autumn-winter peak, was not able to reduce COVID-19 transmission. Moreover, the moderate positive correlation between mask usage and deaths in Western Europe also suggests that the universal use of masks may have had harmful unintended consequences."

[90] **ADDED since 2/8/2022**

Position paper: *Use of facemasks in the community as a means to curb the spread of the COVID-19 virus*

Israeli Public Emergency Council for the Covid19 Crisis

March 31, 2022

https://www.pecc-il.org/_files/ugd/8f392f_a83b55426e6e4ee595c86d1a6c26954e.pdf

About us: "The Public Emergency Council for the Covid19 Crisis is an independent organization made up of leading physicians, researchers and social welfare professionals who, in light of the way that the Covid19 crisis is being managed, have decided that they can no longer remain silent."

"Summary and Recommendation:

1. In light of the lack of clear evidence for the effectiveness of masking in the general public, and testimonies of possible health and environmental damage, we are of the opinion that the use of masks should be limited to its original outline - medical staff wearing masks in specific zones. In other zones, the wearing of masks can be a recommendation, as it is not supported by evidence.

2. The authorities must provide reliable information to the public that will allow each citizen to formulate his or her own risk assessment and make an educated decision on the matter.
3. Regarding children, the recommendation should be against them wearing masks.
4. Mask mandates as a means of 'sending an educational message' or for any purpose other than those of a professional health nature with a proven benefit is unacceptable."

[91] **ADDED since 2/8/2022**

The Foegen effect: A mechanism by which facemasks contribute to the COVID-19 case fatality rates

Medicine
Zacharias Fögen
February 18, 2022
https://journals.lww.com/md-journal/Fulltext/2022/02180/The_Foegen_effect__A_mechanism_by_which_facemasks.60.aspx

"**Abstract**: … This study aimed to determine whether mandatory mask use influenced the case fatality rate in Kansas, USA between August 1st and October 15th 2020…

A parallelization analysis based on county-level data showed that in Kansas, counties with mask mandate had significantly higher case fatality rates than counties without mask mandate, with a **risk ratio of 1.85** (95% confidence interval [95% CI]: 1.51–2.10) **for COVID-19-related deaths**...

These findings suggest that mask use might pose a yet unknown threat to the user instead of protecting them, making mask mandates a debatable epidemiologic intervention.

The cause of this trend is explained herein using the **'Foegen effect' theory**; that is, deep re-inhalation of hypercondensed droplets or pure virions caught in facemasks as droplets can worsen prognosis and might be linked to long-term effects of COVID-19 infection. While the 'Foegen effect' is proven in vivo in an animal model, further research is needed to fully understand it."

[92] **ADDED since 2/8/2022**

Titanium dioxide particles frequently present in face masks intended for general use require regulatory control

Nature Scientific Reports — Sciensano, Belgium
Eveline Verleysen, Marina Ledecq, *et al*.
February 15, 2022
https://www.nature.com/articles/s41598-022-06605-w

"**Abstract**: Although titanium dioxide (TiO2) is a suspected human carcinogen when inhaled, fiber-grade TiO2 (nano)particles were demonstrated in synthetic textile fibers of face masks intended for the general public. STEM-EDX analysis on sections of a variety of single use and reusable face masks visualized agglomerated near-spherical TiO2 particles in non-woven fabrics, polyester, polyamide and bi-component fibers. Median sizes of constituent particles ranged from 89 to 184 nm, implying an important fraction of nano-sized particles (< 100 nm). The total TiO2 mass determined by ICP-OES ranged from 791 to 152,345 µg per mask. The estimated TiO2 mass at the fiber surface ranged from 17 to 4394 µg, and **systematically exceeded the acceptable exposure level to TiO2 by inhalation** (3.6 µg), determined based

on a scenario where face masks are worn intensively…

Introduction: … A recent study, testing several batches of face masks intended to be put on sale as personal protective equipment, showed that **70%** of the examined face masks contained TiO2 in quantities ranging from 100 to 2000 mg kg−12. This suggests that TiO2 is commonly applied in textiles of face masks, as in a wide variety of other textiles, e.g. to improve stability to ultraviolet light, as white colorant or as a matting agent. In addition, to introduce new solutions to the challenges associated with the COVID-19 pandemic, textile companies are incorporating specific nanofiber, nanocomposite and nanoparticle technology into face masks. Nanofibers containing TiO2 nanoparticles have been produced to create antimicrobial filters, also in combination with silver and graphene. Coatings of TiO2 nanoparticles on cotton fabric were applied for enhanced self-cleaning and antibacterial properties.

In their recent opinion paper, Palmeiri *et al*. warn for the possible future consequences caused by a poorly regulated use of nanotechnology in textiles applied to improve the performance of face masks. In animal experiments, **toxic effects** were reported when TiO2 particles were inhaled, as well as when they were ingested orally. In 2017, the Risk Assessment Committee (RAC) of the European Chemical Agency (ECHA) reviewed the carcinogenic potential of TiO2 and proposed to classify Titanium dioxide as Carc. 2, H351 (**suspected human carcinogen**) by inhalation. This CLP classification was adopted for titanium dioxide.

To evaluate whether the TiO2 particles in face masks possibly present a health risk, their amounts, their physicochemical properties and their localization were analyzed in a selection of face masks. Supporting on these measurements, the amount of TiO2 at the surface of the textile fibers was estimated and compared with the acceptable exposure level to TiO2 by inhalation, expressed per mask (AEL_{mask}).

Results and discussion…

Table 1 shows that for all examined face masks, **the amount of TiO2 particles at the surface of the textile fibers notably exceeds the AEL_{mask}**. This systematic exceedance indicates that by applying an approach relying on conservative assumptions while uncertainties regarding hazard and exposure remain (Supplementary Information), a health risk cannot be ruled out when face masks containing polyester, polyamide, thermobonded non-woven and bi-component fibers, are used intensively. Exceedance of the AEL_{mask} for reusable face masks is higher (87 to 1220 times) than for single use masks (5 to 11 times), implying that for the reusable masks uptake of only a very small percentage of the particles at the fiber surface may already pose a health risk."

[93] **ADDED since 2/8/2022**
Letter from a Los Angeles Psychiatrist to his Patients
Mark McDonald, MD
February 2022
https://aflds.org/news/post/psychiatrist-bans-child-masking-and-all-forms-of-child-abuse-in-his-practice/

"Dear Patient Name,

Effective immediately, all forms of child abuse will no longer be tolerated in my office. This includes masking children…

My first ethical responsibility as a physician is to do no harm to my patients, and allowing children to mask their faces has caused and continues to cause tremendous harm to them physically, emotionally, pshychologically, and developmentally. Any argument to the contrary is naïve and irrational.

Over the past year, **referrals to speech and language therapists have increased by between 25 and 300%**, depending on locale. Younger children have suffered a **24% cognitive decline**, along with a 22 IQ-point loss among infants [*emphasis added*], due to a combination of prolonged isolation, anti-social distancing, and universal masking of faces. This catastrophe is mand-made and due entirely to the failings of adults."

[94] ***Kids and Speech Delays***
WPBF (West Palm Beach, FL)
January 26, 2022
https://rumble.com/vtee83-kids-and-speech-delays.html

Reporter: "Jaclyn Theeck says during this pandemic, her speech therapy clinic has seen an enormous shift in the ages of their patients…"

Theeck: "We've seen a 364% increase in patient referrals of babies and toddlers from pediatricians and parents."

Reporter: "And they are children having a difficult time speaking?"

Theeck: "Speech delayed… There's no research out there yet saying that this could be causing speech and language delays, but most definitely it's, I'm sure, a factor. It's very important that kids do see your face to learn, as they're watching your mouth."

[95] **ADDED since 2/8/2022**
Book: *Unmasked: The Global Failure of COVID Mask Mandates*
Ian Miller
January 20, 2022
https://www.amazon.com/Unmasked-Global-Failure-COVID-Mandates/dp/1637583761/

"I've looked at data from all over the world, from the granular county level to entire countries, and have yet to find examples showing clear and sustained benefits to mask mandates…

The data I've gathered and present here covers large segments of the world: North America, Europe, parts of South America, down to the local county level within the United States.

Although any one chart or graph should not be the final conclusion on the outcome of mask mandates, when taken in its totality, the data presents a compelling case that masks and the related policies have failed their most significant test. At no point in human history have masks been worn as widely and consistently as they have since April of 2020. This book makes the case that the great mask wearing experiment failed to achieve its goals."

[96] ***Increased personal protective equipment litter as a result of COVID-19 measures***
Nature Sustainability (University of Portsmouth, UK)
Keiron P. Roberts, Sui C. Phang, *et al*.
December 9, 2021
https://www.nature.com/articles/s41893-021-00824-1

"**Abstract**: Use of personal protective equipment (PPE) increased during the COVID-19 pandemic to reduce virus transmission. Here, we quantitatively analyse emergence of PPE and COVID-19-related litter over 14 months for 11 countries using the litter collection application Litterati. The proportion of masks in litter increased by >80-fold as a result of COVID-19 legislation, from <0.01% to >0.8%. Gloves and wipes, more prevalent at ~0.2% of litter before the pandemic, doubled to 0.4%...

Short-term impacts: Within the first few hours and days, **littered PPE and wipes pose a potential viral vector of COVID-19** if used by an infected person [*emphasis added*]…

Long-term impacts: Once in the environment, littered items can continue to have the impacts mentioned above, with the addition of **becoming vectors for other pathogens and pollutants** [*emphasis added*]. Chemical, physical and biological weathering will break the littered items down from macro-plastics (>5 mm) into micro-plastics (<0.5 mm) and nano-plastics (<100 nm) that have the potential to enter the lower food chain and have toxicological effects including the leaching of metals."

[97] ***COVID-19 Masks: How Effective and How Safe?***
Dr. John Droz, Jr., editor
November 21, 2021
https://c19science.info/COVID-19_Masks.pdf
Description: This report includes 100+ links to and excerpts from scientific studies on the efficacy and safety of masks.

[98] **ADDED since 2/8/2022**
Pilot study on burden of fungal contamination in face masks: need for better mask hygiene in the COVID-19 era
Le Infezioni in Medicina — All India Institute of Medical Sciences
Vishakh C. Keri, Arvind Kumar, *et al*.
November 20, 2021
https://www.infezmed.it/media/journal/Vol_29_4_2021_8.pdf

"**Summary**: Risk factors which led to the outbreak of COVID-19 associated Mucormycosis still remains elusive. Face masks can become contaminated by fungal spores that are present ubiquitously in the environment. However the exact burden of such contamination is not known. Fifty masks of patients who attended the Employees Health Scheme COVID-19 facility of a tertiary healthcare centre in India were sampled by direct impression smears on Sabouraud Dextrose Agar…

Out of 50 masks, **fungal contamination was seen in 35/50 (70%) masks**, with *Aspergillus sp.* being isolated from 26/50 (52%) masks and Mucorales being isolated from 9/50 (18%) of the masks. *Aspergillus niger*, *Rhizopus arrhizus* and *Syncephalastrum sp.* were the most common species isolated…

High rates of fungal contamination observed in our study emphasizes the need for better mask hygiene in the COVID-19 era."

[99] ***Plastic waste release caused by COVID-19 and its fate in the global ocean***
PNAS (Nanking University)
Yiming Peng, Peipei Wu, Amina T. Schartup, and Yanxu Zhang
November 8, 2021
https://www.pnas.org/content/118/47/e2111530118

"**Abstract**: The COVID-19 pandemic has led to an increased demand for single-use plastics that intensifies pressure on an already out-of-control global plastic waste problem. While it is suspected to be large, the magnitude and fate of this pandemic-associated mismanaged plastic waste are unknown. Here, we use our MITgcm ocean plastic model to quantify the impact of the pandemic on plastic discharge. We show that 8.4 ± 1.4 million tons of pandemic-associated plastic waste have been generated from 193 countries as of August 23, 2021, with 25.9 ± 3.8 thousand tons released into the global ocean representing 1.5 ± 0.2% of the global total riverine plastic discharge."

[100] ***Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review***
Cato Institute
Ian T. Liu, Vinay Prasad, and Jonathan J. Darrow
November 8, 2021
https://www.cato.org/sites/cato.org/files/2021-11/working-paper-64.pdf

"**Abstract**: The use of cloth facemasks in community settings has become an accepted public policy response to decrease disease transmission during the COVID-19 pandemic. Yet evidence of facemask efficacy is based primarily on observational studies that are subject to confounding and on mechanistic studies that rely on surrogate endpoints (such as droplet dispersion) as proxies for disease transmission. The available clinical evidence of facemask efficacy is of low quality and the best available clinical evidence has mostly failed to show efficacy, with **fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit** in the intent-to-treat populations [*emphasis added*]. Of sixteen quantitative meta-analyses, eight were equivocal or critical as to whether evidence supports a public recommendation of masks, and the remaining eight supported a public mask intervention on limited evidence primarily on the basis of the precautionary principle. Although weak evidence should not preclude precautionary actions in the face of unprecedented events such as the COVID-19 pandemic, ethical principles require that the strength of the evidence and best estimates of amount of benefit be truthfully communicated to the public."

[101] ***Risks of Covid-19 face masks to wildlife: Present and future research needs***
Science of the Total Environment (University of Aveiro, Portugal)
Ana L. Patricio Silva, Joana C. Prata, *et al*.
October 20, 2021
https://www.sciencedirect.com/science/article/pii/S0048969721035774

"**3. Disposable masks can directly threaten wildlife**

It is widely recognised that plastic pollution can directly affect wildlife (e.g., via ingestion and entanglement), regardless of their habitat, physiology, behavioural patterns. Over 200 species, including marine mammals, sea turtles, and seabirds, are reported to have been entangled or ingested plastic litter (Kühn et al., 2015). Both ingestion and entanglement can be detrimental to the organisms' survival and reproduction by limiting their mobility and feeding ability…

4. Potential ecotoxicological effects

Once in open environments, single-use-masks will likely undergo fragmentation by physicochemical (e.g., UV radiation, wind, currents) and biochemical (enzymatic activity) processes (Fadare and Okoffo, 2020; Prata et al., 2020), resulting in a myriad of small particles such as micro- and nano-plastics (< 5 mm in size and < 1um in size, respectively; Frias and Nash, 2019). The few monitoring studies on PPE in the environment (summarized in Table 1) evaluated the weathered/deterioration levels of these items (FTIR, SEM), which suggests the release of plastic fibres and microplastics…

5. Final remarks and future recommendations

… [I]ntense use and mismanagement of COVID-19 waste are imposing a severe environmental challenge. Thousands of tons of disposable face masks are ending up in natural environments worldwide; where they can scale up microfibres and hazardous chemicals contamination, with the potential to induce severe effects on their inhabitants, from invertebrates to vertebrates and at different levels of biological systems."

[102] ***Investigating the current status of COVID-19 related plastics and their potential impact on human health***
Current Opinion in Toxicology (Universidad San Ignacio de Loyola, Peru)
Gabriel EnriqueDe-la-Torre, Carlos Ivan Pizarro-Ortega, Diana Carolina Dioses-Salinas, JustineAmmendolia, and Elvis D.Okoffo
August 13, 2021
https://www.sciencedirect.com/science/article/pii/S2468202021000371

"**Abstract**: The COVID-19 pandemic led to a sudden global increase in the production, consumption, and mismanagement of personal protective equipment (PPE). As plastic-based PPE such as disposable face masks and gloves have become widely used, human exposure to PPE-derived pollutants may occur through indirect and direct pathways. This review explores the potential health impacts related to plastic-based PPE through these pathways. **Face masks release microplastics, which are directly inhaled during use** or **transported through the environment**. The latter can adsorb chemical contaminants and harbor pathogenic microbiota, and once consumed by organisms, they can translocate to multiple organs upon intake, potentially causing detrimental and cytotoxic effects [*emphasis added*]."

[103] ***Mask mandate and use efficacy for COVID-19 containment in US States***
medRxiv
Damian D. Guerra and Daniel J. Guerra
August 7, 2021
https://www.medrxiv.org/content/10.1101/2021.05.18.21257385v1.full

> "**Discussion**: Our main finding is that mask mandates and use are not associated with lower SARS-CoV-2 spread among US states. 80% of US states mandated masks during the COVID-19 pandemic. Mandates induced greater mask compliance but did not predict lower growth rates when community spread was low (minima) or high (maxima)…
>
> In summary, mask mandates and use were poor predictors of COVID-19 spread in US states. Case growth was independent of mandates at low and high rates of community spread, and **mask use did not predict case growth** during the Summer or Fall-Winter waves [*emphasis added*]."

[104] ***47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effects***
July 23, 2021
https://www.lifesitenews.com/news/47-studies-confirm-inefectiveness-of-masks-for-covid-and-32-more-confirm-their-negative-health-effects/

[105] ***Covid: Disposable masks pose pollutants risk, study finds***
BBC News
May 4, 2021
https://www.bbc.com/news/uk-wales-56972074

> "The Swansea University team found heavy metals and plastic fibres were released when throw-away masks were submerged in water…
>
> Back in November last year, the researchers were only originally interested in the plastic waste impact on our environment. But as they tested more and more masks, they uncovered more chemicals…
>
> The team found traces of lead, antimony and cadmium - all heavy metals which can be toxic in low doses…
>
> He [*Dr Geraint Sullivan*] said the heavy metals found were also 'bio-accumulative', which means they are not removed from aquatic systems and they build up over time.
>
> Every mask tested leached chemicals when submerged."

[106] **Video (3m): *Do Masks Work? Viral immunologist Dr. Byram Bridle performs a simple experiment to see.***
April 24, 2021
https://www.youtube.com/watch?v=tIaul0U83d0

> "As a scientist, I'm going to present the facts and let people draw their own conclusions… With a lot of respiratory pathogens, they get transmitted through large water droplets, especially when we cough and sneeze. Now the primary mode of transmission of SARS-CoV-2 is through aerosols.

There are three sizes of water droplets that can come out of your lungs. Large droplets … that are over 60 microns. They have this trajectory under gravity where they quickly fall to the ground. Then there's small water droplets that are between 10 and 60 microns in diameter. And then there's what we call 'droplet nuclei,' which are smaller than 10 microns. So when we talk about aerosols, we're talking about these droplet nuclei and small droplets.

If you want to visualize it, when you go out in cold air in the middle of winter when you can see your breath, that's the aerosols. That's the aerosol condensing in the air. And it doesn't just drop to the ground…

Scientific studies before this pandemic have shown that low-cost masks — so we're talking about surgical masks and the cloth masks we're wearing … have pore sizes that range between 80 and 500 microns in size. The diameter of the virus is 1 micron. The largest possible small droplet for an aerosol is 62 microns in diameter. So let's put that in perspective. The smallest pore size is 80, so that means the largest droplet with the virus can pass right through."

[107] ***Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?***
International Journal of Environmental Research and Public Health
Kai Kisielinski, Paul Gibon, *et al*.
April 20, 2021
https://www.mdpi.com/1660-4601/18/8/4344/htm

"**Abstract**: … We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O2 drop (67%), N95 mask and CO2 rise (82%), N95 mask and O2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields."

[108] **The 'Danish Study': *Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers. A Randomized Controlled Trial*.**
Annals of Internal Medicine
Henning Bundgaard, Johan Skov Bundgaard, *et al*.
March 2021
https://www.acpjournals.org/doi/10.7326/M20-6817

"**Results**: A total of 3030 participants were randomly assigned to the recommendation to wear masks, and 2994 were assigned to control; 4862 completed the study. Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%)... Although the difference observed was not statistically significant, the 95% CIs are compatible with a 46% reduction to a 23% increase in infection."

Discussion: "Our results suggest that the recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, the incidence of SARS-CoV-2 infection in mask wearers in a setting where social distancing and other public health measures were in effect…"

[109] ***Review of scientific reports of harms caused by face masks, up to February 2021***
Denis Rancourt
February 22, 2021
https://denisrancourt.ca/entries.php?id=15&name=2021_02_22_review_of_scientific_reports_of_harms_caused_by_face_masks_up_to_february_2021

> "[H]arms from prolonged masking are increasingly being documented in many scientific studies, especially in the areas of healthcare workers, school children, newborn infants, and bacterial infections in the general population, as described below."

[110] ***Using face masks in the community: first update***
European Centre for Disease Prevention and Control
February 15, 2021
https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-face-masks-community-first-update.pdf

> "**Assessment of the evidence**: The evidence regarding the effectiveness of medical face masks for the prevention of COVID-19 in the community is compatible with a small to moderate protective effect, but there are still significant uncertainties about the size of this effect. Evidence for the effectiveness of non-medical face masks, face shields/visors and respirators in the community is **scarce** and of **very low certainty** [*emphasis added*]."

[111] ***Masking: A Careful Review of the Evidence***
AIER
Paul E. Alexander
February 11, 2021
An analysis of the scientific literature on the effectiveness of face masks and related policies/issues.
https://www.aier.org/article/masking-a-careful-review-of-the-evidence/

> "**Predominant finding?** The predominant conclusion is that face masks have a very important role in places such as hospitals, but there exists very little evidence of widespread benefit for members of the public (adults or children), as well as evidence that masking is truly an ineffectual way to manage pandemic-related spread of viral disease…"
>
> "Our view is that masks as they are worn now, and the masks that are in use, offer zero protection… We state emphatically that public health policy, or any policy for that matter, must be undergirded by sound data and evidence. As we have said, the reality is that widespread use of masks is not supported by science and in fact just the opposite."
>
> "**Conclusion**: In sum, when we look at the science, there is emerging and troubling evidence of harms from mask use in the absence of any benefits."

[112] ***Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study***
The Lancet – Infectious Diseases
Michael Marks, Pere Millat-Martinez, *et al*.
February 2, 2021
https://www.thelancet.com/journals/laninf/issue/vol21no5/PIIS1473-3099(21)X0005-9

> "[W]e did not note any association between mask use and risk either in our unadjusted analysis (table 3) or in a multivariable model excluding type of exposure."

[113] **ADDED since 2/8/2022**

Face masks and nanotechnology: Keep the blue side up

Nano Today — Fondazione Policlinico Universitario, Italy

Valentina Palmieri, Flavio De Maio, Marco De Spirito, and Massimillano Papi

January 13, 2021

https://www.sciencedirect.com/science/article/pii/S1748013221000025

> "Nanomaterials already available in face masks on the market include copper dioxide, carbon, graphene, nanodiamonds, nanosilver and titanium dioxide, a list of patented antiviral technologies from Campos and colleagues is reported…
>
> Although originally classified as biologically inert, there is a growing body of evidence on the **toxicity of TiO2** to humans and non-target organisms, as recently outlined by Luo and colleagues,,,
>
> Artificial sweat was also used to test the concentration of the silver and TiO2 released from fabrics. The release rate was found to depend on the concentration of nanomaterials in the fabric and the pH of sweat."

[114] ***"Exercise with facemask; Are we handling a devil's sword?" – A physiological hypothesis***

Medical Hypotheses

Baskaran Chandrasekaran and Shifra Fernandes

November 2020

https://www.sciencedirect.com/science/article/abs/pii/S0306987720317126?via%3Dihub

> "**Abstract**: Though WHO supports facemasks only for Covid-19 patients, healthy 'social exercisers' too exercise strenuously with customized facemasks or N95 which hypothesized to pose more significant health risks and tax various physiological systems especially pulmonary, circulatory and immune systems. Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment, cardiac overload, anaerobic metabolism and renal overload, which may substantially aggravate the underlying pathology of established chronic diseases. Further contrary to the earlier thought, no evidence exists to claim the facemasks during exercise offer additional protection from the droplet transfer of the virus."

[115] **ADDED since 2/8/2020**

Physical interventions to interrupt or reduce the spread of respiratory viruses

Cochrane Database of Systematic Reviews — Institute for Evidence-Based Healthcare

Tom Jefferson, Chris B. Del Mar, *et al*.

November 20, 2020

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub5/full

> "**Objectives**: To assess the effectiveness of physical interventions to interrupt or reduce the spread of acute respiratory viruses.
>
> **Search methods**: We searched CENTRAL, PubMed, Embase, CINAHL on 1 April 2020. We searched ClinicalTrials.gov, and the WHO ICTRP on 16 March 2020. We conducted a backwards and forwards citation analysis on the newly included studies.

Selection criteria: We included randomised controlled trials (RCTs) and cluster - RCTs of trials investigating physical interventions (screening at entry ports, isolation, quarantine, physical distancing, personal protection, hand hygiene, face masks, and gargling) to prevent respiratory virus transmission. In previous versions of this review we also included observational studies. However, for this update, there were sufficient RCTs to address our study aims...

Main results: We included 44 new RCTs and cluster - RCTs in this update, bringing the total number of randomised trials to 67…

Medical/surgical masks compared to no masks: We included nine trials (of which eight were cluster - RCTs) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness (two trials with healthcare workers and seven in the community). There is low certainty evidence from nine trials (3507 participants) that wearing a mask may make little or no difference to the outcome of influenza-like illness (ILI) compared to not wearing a mask (risk ratio (RR) 0.99, 95% confidence interval (CI) 0.82 to 1.18. There is **moderate certainty evidence** that wearing a mask probably makes little or no difference to the outcome of laboratory-confirmed influenza compared to not wearing a mask (RR 0.91, 95% CI 0.66 to 1.26; 6 trials; 3005 participants). Harms were rarely measured and poorly reported."

[116] ***Masks are neither effective nor safe: A summary of the science***
Primary Doctor Medical Journal
Colleen Huber
Completed peer-review and revised, November 19, 2020
https://pdmj.org/papers/masks_are_neither_effective_nor_safe

"**Abstract**: A review of the peer-reviewed medical literature examines impacts of masks on human health, both immunological, as well as physiological. The purpose of this paper is to examine data regarding the effectiveness of facemasks, as well as safety data…

Weighing risk versus benefit of mask use…

The use of face masks, whether cloth, surgical or N95, creates a **poor obstacle** to aerosolized pathogens as we can see from the meta-analyses and other studies in this paper, **allowing both transmission of aerosolized pathogens to others** in various directions, as well as **self-contamination** [*emphasis added*]. Forward projection of exhaled material may be partly replaced by lateral, backward, downward and upward projection, and to greater distances, with longer time airborne, from a masked person than from an unmasked person.

It must also be considered that masks impede the necessary volume of air intake required for adequate oxygen / carbon dioxide exchange, which results in observed physiological effects that may be undesirable. Even 6-minute walks, let alone more strenuous activity, resulted in 7 dyspnea. The volume of unobstructed oxygen in a typical breath is about 100 ml, used for normal physiological processes. 100 ml O2 greatly exceeds the volume of a pathogen required for transmission.

The foregoing data show that masks serve more as instruments of obstruction of normal breathing, rather than as effective barriers to pathogens. Therefore, masks should not be used by the general public, either by adults or children, and their limitations as prophylaxis against pathogens should also be considered in medical settings. The clinical studies and meta-

analyses that are referenced, cited and linked herein are presented in order to provide the best opportunity for informed decision-making, and for individuals to consider and compare the risks versus benefits of mask use."

[117] ***Masks, false safety and real dangers***
Primary Doctor Medical Journal
Boris Borovoy, Colleen Huber, Q Makeeta, and Maria Crisler
Completed peer-review and revised, November 19, 2020
Part 1: Friable mask particulate and lung vulnerability:
https://pdmj.org/papers/masks_false_safety_and_real_dangers_part1
Part 2: Microbial challenges from masks
https://pdmj.org/papers/masks_false_safety_and_real_dangers_part2
Part 3: Hypoxia, hypercapnia and physiological effects
https://pdmj.org/papers/masks_false_safety_and_real_dangers_part3
Part 4: Proposed mechanisms by which masks increase risk of COVID-19
https://pdmj.org/papers/masks_false_safety_and_real_dangers_part4

[118] **ADDED since 2/8/2020**
WITHDRAWN: *Decrease in Hospitalizations for COVID-19 after Mask Mandates in 1083 U.S. Counties*
Massachusetts Institute of Technology and University of California, San Francisco
Dhaval Adjodah, Karthik Dinakar, *et al*.
November 4, 2020
https://www.medrxiv.org/content/10.1101/2020.10.21.20208728v2

"**Abstract**

Withdrawal. The authors have withdrawn this manuscript because there are increased rates of SARS- CoV-2 cases in the areas that we originally analyzed in this study. New analyses in the context of the third surge in the United States are therefore needed and will be undertaken directly in conjunction with the creators of the publicly-available databases on cases, hospitalizations, testing rates. Etc. We will be performing this in conjunction with machine learning experts at UCSF. Therefore, the authors do not wish this work to be cited as reference for the project. We hope to have an updated analysis using data from the 2nd and now 3rd wave of SARS-CoV-2 in this country soon."

[119] **ADDED since 2/8/2020**
Safety and Health Guidance: COVID-19 Infection Prevention for Logistics Employers and Employees
California Department of Industrial Relations, Division of Occupational Safety & Health
October 27, 2020
https://www.dir.ca.gov/dosh/coronavirus/COVID-19-Infection-Prevention-in-Logistics.pdf

"Cloth face covers are not protective equipment and do not protect the person wearing a cloth face cover from COVID-19."

[120] ***Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster-randomized trial***
PLOS One
Mohammad Alfelali, Elizabeth A. Haworth, *et al*.
October 13, 2020
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0240287

"**Background**: In this large-scale cluster-randomized controlled trial (cRCT) we sought to assess the effectiveness of facemasks against viral respiratory infections.

Method and results: … By intention-to-treat analysis, facemask use did not seem to be effective against laboratory-confirmed viral respiratory infections… nor against clinical respiratory infection."

[121] ***An Evidence Based Scientific Analysis of Why Masks are Ineffective, Unnecessary, and Harmful***
Jim Meehan
October 10, 2020
https://ratical.org/PandemicParallaxView/mp3s/An-Evidence-Based-Scientific-Analysis-of-Why-Masks-are-Ineffective-Unnecessary-and-Harmful-10-12-2020.pdf

Pages 27-39: *Masks are Harmful: 17 Ways That Masks Can Cause Harm* (includes embedded links to primary sources):

1. Medical masks adversely affect respiratory physiology and function
2. Medical masks lower oxygen levels in the blood
3. Medical masks raise carbon dioxide levels in the blood…
4. SARS CoV-2 is armed with a "furin cleavage site" that makes it more pathogenic
5. Medical masks trap exhaled viral (and other) pathogens in the mouth/mask interspace, increase viral/infectious load, and increase the severity of disease
6. SARS CoV-2 Becomes More Dangerous When Blood Oxygen Levels Decline
7. The furin cleavage site of SARS CoV-2 increases cellular invasion, especially during hypoxia (low blood oxygen levels)
8. Cloth masks may increase the risk of contracting Covid-19 and other respiratory infections
9. Wearing a face mask may give a false sense of security
10. Masks compromise communications and reduce social distancing
11. Untrained and inappropriate management of face masks
12. Masks Worn Imperfectly Are Dangerous
13. Masks collect and colonize viruses, bacteria, and mold

14. Wearing a face mask makes the exhaled air (respiratory plumes) go into the eyes

15. Contact tracing studies show that asymptomatic carrier transmission is very rare

16. Face masks and stay at home orders prevent the development of herd immunity

17. Face masks are dangerous and contraindicated for a large number of people with pre-existing medical conditions and disabilities

[122] ***Medical Doctor Warns that "Bacterial Pneumonias Are on the Rise" from Mask Wearing***
Global Research
John C.A. Manley
October 6, 2020
https://www.globalresearch.ca/medical-doctor-warns-bacterial-pneumonias-rise-mask-wearing

> "Dr. James Meehan, MD [warned] that mask wearing has 'well-known risks that have been well-studied and they're not being discussed in the risk analysis.'
>
> 'I'm seeing patients that have facial rashes, fungal infections, bacterial infections. Reports coming from my colleagues, all over the world, are suggesting that the bacterial pneumonias are on the rise.
>
> 'Why might that be? Because untrained members of the public are wearing medical masks, repeatedly… in a non-sterile fashion… They're becoming contaminated. They're pulling them off of their car seat, off the rearview mirror, out of their pocket, from their countertop, and they're reapplying a mask that should be worn fresh and sterile every single time.'"

[123] ***Open letter from medical doctors and health professionals to all Belgian authorities and all Belgian media***
September 20, 2020
https://www.aier.org/article/open-letter-from-medical-doctors-and-health-professionals-to-all-belgian-authorities-and-all-belgian-media/
Signatories: https://docs4opendebate.be/en/signatories/

> "[T]he following letter has made an impact on public health authorities not only in Belgium but around the world… So far it has been signed by 394 medical doctors, 1,340 medically trained health professionals, and 8,897 citizens."
>
> Letter excerpts:
>
> "Oral masks belong in contexts where contacts with proven at-risk groups or people with upper respiratory complaints take place, and in a medical context/hospital-retirement home setting. They reduce the risk of droplet infection by sneezing or coughing. Oral masks in healthy individuals are ineffective against the spread of viral infections.
>
> Wearing a mask is not without side effects. Oxygen deficiency (headache, nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems and hyperventilation due to wearing masks. In addition, the accumulated CO2 leads to a toxic acidification of the organism which affects our immunity. **Some experts even warn of an increased transmission of the virus** in case of inappropriate use of the mask [*emphasis*

added].

Our Labour Code (Codex 6) refers to a CO2 content (ventilation in workplaces) of 900 ppm, maximum 1200 ppm in special circumstances. After wearing a mask for one minute, this toxic limit is considerably exceeded to values that are three to four times higher than these maximum values. Anyone who wears a mask is therefore in an extreme poorly ventilated room."

[124] ***Psychosocial, biological, and immunological risks for children and pupils make long-term wearing of mouth masks difficult to maintain***
British Medical Journal – Rapid Response
Carla Peeters, Wim Vanden Berghe, and Mattias Desmet
August 19, 2020
https://www.bmj.com/content/370/bmj.m3021/rr-6

"This rapid response considers **the negative effects at the immunological and psychological level of mandating facemasks for children** and adolescents and maintains that they outweigh the possible gains [*emphasis added*]…

2. Facemasks at school: a slippery slope from virus protection to mental breakdown? … At the outset of the pandemic, WHO experts advised that use of facemasks is not recommended as potential benefits are rather limited and there is a **potential risk of self-contamination if used improperly** [*emphasis added*]. Moreover the WHO stated in their report of June 5 'At present, there is no direct evidence (from studies on Covid19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including Covid19. Contamination of the upper respiratory tract by viruses and bacteria on the outside of medical face masks has been detected in several hospitals. Another research shows that a moist mask is a breeding ground for (antibiotic resistant) bacteria and fungi, which can undermine mucosal viral immunity…

Several studies show that long-term exposure to socio-psychological stress leaves neuro-epigenetic scars that are difficult to cure in young people and often escalate into mental behavioural problems and a weakened immune system. A recent study by the CDC concludes that in young adults (18-24 years), the level of anxiety and **depression has increased by 63%** since the corona crisis. A quarter of them think about suicide [*emphasis added*]. As a result, the use of antidepressants has increased by 25%. Several researchers have shown a relationship between the increase in stress experiences and the risk of upper respiratory tract infections and mortality."

[125] ***Increased plastic pollution due to COVID-19 pandemic: Challenges and recommendations***
Chemical Engineering Journal
Joana C. Prata, Ana L.P. Silva, *et al*.
August 17, 2020
https://www.sciencedirect.com/science/article/abs/pii/S1385894720328114

"**Abstract**: Plastics have become a severe transboundary threat to natural ecosystems and human health, with studies predicting a twofold increase in the number of plastic debris (including micro and nano-sized plastics) by 2030. However, such predictions will likely be aggravated by the excessive use and consumption of single-use plastics (including personal protective equipment such as masks and gloves) due to COVID-19 pandemic. This review

aimed to provide a comprehensive overview on the effects of COVID-19 on macroplastic pollution and its potential implications on the environment and human health considering short- and long-term scenarios…"

[126] **ADDED since 2/8/2022**
Rethinking Nano-TiO2 Safety: Overview of Toxic Effects in Humans and Aquatic Animals
Nano-Micro Small — Shanghai Ocean University, China
Zhen Luo, Zhuoqing Li, *et al*.
August 6, 2020
https://onlinelibrary.wiley.com/doi/abs/10.1002/smll.202002019

Note: As reported by Nature, titanium dioxide particles are "frequently present in face masks intended for general use." See [92].

"**Abstract**: Titanium dioxide nanoparticles (nano-TiO2) are widely used in consumer products, raising environmental and health concerns. An overview of the toxic effects of nano-TiO2 on human and environmental health is provided. A meta-analysis is conducted to analyze the toxicity of nano-TiO2 to the liver, circulatory system, and DNA in humans. To assess the environmental impacts of nano-TiO2, aquatic environments that receive high nano-TiO2 inputs are focused on, and the toxicity of nano-TiO2 to aquatic organisms is discussed with regard to the present and predicted environmental concentrations. **Genotoxicity**, **damage to membranes**, **inflammation** and **oxidative stress** emerge as the main mechanisms of nano-TiO2 toxicity. Furthermore, nano-TiO2 can bind with free radicals and signal molecules, and interfere with the biochemical reactions on plasmalemma… The possible measures to reduce the harmful effects of nano-TiO2 on humans and non-target organisms has emerged as an underexplored topic requiring further investigation."

[127] ***COVID-19 Pandemic Repercussions on the Use and Management of Plastics***
Environmental Science & Technology
Joana C. Prata, Ana L.P. Silva, *et al*.
June 12, 2020
https://pubs.acs.org/doi/full/10.1021/acs.est.0c02178

"**Abstract**: Mismanagement of personal protective equipment (PPE) during the COVID-19 pandemic, with a monthly estimated use of 129 billion face masks and 65 billion gloves globally, is resulting in widespread environmental contamination. This poses a risk to public health as **waste is a vector for SARS-CoV-2 virus** [*emphasis added*]..."

[128] ***Advice on the use of masks in the context of COVID-19***
World Health Organization
June 5, 2020
https://apps.who.int/iris/bitstream/handle/10665/332293/WHO-2019-nCov-IPC_Masks-2020.4-eng.pdf?sequence=1&isAllowed=y

"At present, there is no direct evidence (from studies on COVID-19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including COVID-19…

[T]he widespread use of masks by healthy people in the community setting is **not yet supported by high quality or direct scientific evidence** and **there are potential benefits and harms to consider** [*emphasis added*]…"

Potential harms/disadvantages

The likely disadvantages of the use of mask by healthy people in the general public include:

- potential increased risk of self-contamination due to the manipulation of a face mask and subsequently touching eyes with contaminated hands;
- potential self-contamination that can occur if non-medical masks are not changed when wet or soiled. This can create favourable conditions for microorganism to amplify;
- potential headache and/or breathing difficulties, depending on type of mask used;
- potential development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours; …
- waste management issues; improper mask disposal leading to increased litter in public places, risk of contamination to street cleaners and environment hazard; …

[129] **ADDED since 2/8/2020**
Perspective: Universal Masking in Hospitals in the Covid-19 Era
New England Journal of Medicine — Harvard Medical School
Michael Klompas, Charles A. Morris, Julia Sinclair, Madelyn Pearson, and Erica S. Shenoy
May 21, 2020
https://www.nejm.org/doi/full/10.1056/nejmp2006372

"We know that wearing a mask outside health care facilities offers little, if any, protection from infection."

[130] ***Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures***
CDC Emerging Infectious Diseases
Jingyi Xiao, Eunice Y.C. Shiu, *et al*.
May 2020
https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article

"**Face Masks**: … In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks…

Disposable medical masks (also known as surgical masks) are loose-fitting devices that were designed to be worn by medical personnel to protect accidental contamination of patient wounds, and to protect the wearer against splashes or sprays of bodily fluids. There is limited evidence for their effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found **no significant effect of face masks on transmission of laboratory-confirmed influenza** [*emphasis added*]."

[131] ***Covid-19: important potential side effects of wearing face masks that we should bear in mind***
British Medical Journal – Rapid Response
Antonio Lassarino, A. Steptoe, M. Harner, and S. Michie
April 9, 2020
https://www.bmj.com/content/369/bmj.m1435/rr-40

> "Most scientific articles and guidelines in the context of the covid-19 pandemic highlight two potential side effects of wearing surgical face masks in the public, but we believe that there are other ones that are worth considering before any global public health policy is implemented involving billions of people.
>
> The two potential side effects that have already been acknowledged are: …
>
> (1) Wearing a face mask may give a false sense of security and make people adopt a reduction in compliance with other infection control measures, including social distancing and hands washing.
>
> (2) Inappropriate use of face mask: people must not touch their masks, must change their single-use masks frequently or wash them regularly, dispose them correctly and adopt other management measures, **otherwise their risks and those of others may increase** [*emphasis added*].
>
> Other potential side effects that we must consider are: …
>
> (4) Wearing a face mask makes the exhaled air go into the eyes. This generates an uncomfortable feeling and an impulse to touch your eyes. If your hands are contaminated, you are infecting yourself.
>
> (5) Face masks make breathing more difficult. For people with COPD, face masks are in fact intolerable to wear as they worsen their breathlessness. Moreover, a fraction of carbon dioxide previously exhaled is inhaled at each respiratory cycle. Those two phenomena increase breathing frequency and deepness, and hence they increase the amount of inhaled and exhaled air. This may worsen the burden of covid-19 if infected people wearing masks spread more contaminated air. This may also worsen the clinical condition of infected people if the enhanced breathing pushes the viral load down into their lungs.
>
> (5B) The effects described at point 5 are amplified **if face masks are heavily contaminated** [*emphasis added*].
>
> (6) The innate immunity's efficacy is highly dependent on the viral load. If face masks determine a humid habitat where the SARS-CoV-2 can remain active due to the water vapour continuously provided by breathing and captured by the mask fabric, they determine an increase in viral load and therefore they can cause a **defeat of the innate immunity** and **an increase in infections** [*emphasis added*].
>
> It is necessary to quantify the complex interactions that may well be operating between positive and negative effects of wearing surgical masks at population level. It is not time to act without evidence."

[132] **ADDED since 2/8/2022**
Video (1m): *Surgeon General shows how to make face masks*
Presentation by Jerome Adams, US Surgeon General
April 4, 2020
https://www.youtube.com/watch?v=9YLXEhSjVsw

> "Here's how you can make your own face covering in a few easy steps with items you can find around the house like an old scarf, a bandana, or a hand towel, or you can make a face covering out of an old t-shirt."

[133] ***Masks Don't Work: A review of science relevant to COVID-19 social policy***
D.G. Rancourt
April 2020
https://www.rcreader.com/sites/default/files/Denis%20G.%20Rancourt%20PhD%20April%202020%20%22Masks%20Don%27t%20Work%3A%20A%20review%20of%20science%20relevant%20to%20COVID-19%20social%20policy%22.pdf

> "**Unknown Aspects of Mask Wearing**: Many potential harms may arise from broad public policies to wear masks, and the following unanswered questions arise:
>
> - Do used and loaded masks become sources of enhanced transmission, for the wearer and others?
> - Do masks become collectors and retainers of pathogens that the mask wearer would otherwise avoid when breathing without a mask?
> - Are large droplets captured by a mask atomized or aerolized into breathable components? Can virions escape an evaporating droplet stuck to a mask fiber?
> - What are the dangers of bacterial growth on a used and loaded mask?
> - How do pathogen-laden droplets interact with environmental dust and aerosols captured on the mask?
> - What are long-term health effects on HCW, such as headaches, arising from impeded breathing?
> - Are there negative social consequences to a masked society?
> - Are there negative psychological consequences to wearing a mask, as a fear-based behavioural modification?
> - What are the environmental consequences of mask manufacturing and disposal?
> - Do the masks shed fibres or substances that are harmful when inhaled?"

[134] ***Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis***
Journal of Evidence-Based Medicine
Youlin Long, Tengyue Hu, *et al*.
March 13, 2020
https://onlinelibrary.wiley.com/doi/10.1111/jebm.12381

"**Objective**: Previous meta-analyses concluded that there was insufficient evidence to determine the effect of N95 respirators. We aimed to assess the effectiveness of N95 respirators versus surgical masks for prevention of influenza by collecting randomized controlled trials (RCTs)…

Results: A total of six RCTs involving 9 171 participants were included. There were no statistically significant differences in preventing laboratory-confirmed influenza (RR = 1.09, 95% CI 0.92-1.28, P > .05), laboratory-confirmed respiratory viral infections (RR = 0.89, 95% CI 0.70-1.11), laboratory-confirmed respiratory infection (RR = 0.74, 95% CI 0.42-1.29) and influenzalike illness (RR = 0.61, 95% CI 0.33-1.14) using N95 respirators and surgical masks. Meta-analysis indicated a protective effect of N95 respirators against laboratory-confirmed bacterial colonization (RR = 0.58, 95% CI 0.43-0.78).

Conclusion: The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be recommended for general public and nonhigh-risk medical staff those are not in close contact with influenza patients or suspected patients."

[135] **ADDED since 2/8/2022**
Video (1m): Dr. Anthony Fauci talks with Dr Jon LaPook about COVID-19
60 Minutes
March 8, 2020
https://www.youtube.com/watch?v=PRa6t_e7dgI

LaPook: "There's a lot of confusion among people and confusion surrounding face masks. Can you discuss that?

Fauci: "The masks are important for someone who's infected to prevent them from infecting someone else. Now, when you see people and look at the films in China and South Korea whatever, everybody's wearing a mask. Right now in the United States people should not be walking around with masks."

LaPook: "You're sure of it? Because people are listening really closely to this."

Fauci: "Right now, people should not be worried. There's no reason to be walking around with a mask. When you're in the middle of an outbreak, wearing a mask might make people feel a little bit better and it might even block a droplet but it's not providing the perfect protection that people think that it is. And often there are **unintended consequences**. People keep fiddling with the mask and they keep touching their face."

LaPook: "And can you get some schmutz sort of staying inside there?"

Fauci: "Of course, but when you think mask you should think of health care providers needing them and people who are ill. The people who when you look at the films of foreign countries and you see 85% of the people wearing masks that's fine, that's fine. I'm not against it if you want to do it that's fine."

LaPook: "But it can lead to a shortage of masks?"

Fauci: "Exactly. That's the point. It could lead to a shortage of masks for the people who really need it."

[136] ***Contamination by respiratory viruses on outer surface of medical masks used by hospital healthcare workers***
BioMed Central Infectious Diseases
Abrar Ahmad Chughtai, Sacha Stelzer-Braid, *et al*.
June 3, 2019
https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-019-4109-x

"**Discussion**: To our knowledge this is the first study examining the presence of respiratory viruses on the outer surface of used medical masks…

In this study, the risk of mask contamination was associated with duration of masks use and number of patients seen. Currently there is no standard duration for the time period that facemasks and respirators can safely be used. Theoretically, there may be a risk of infection in wearer if contaminated masks are used for prolonged time. Currently there are no data around risk associated with reuse and extended used of masks and other PPE…

[W]hether the measures in the prevention of bacterial shed from the surgical personnel can become the source of bacterial contamination is worth being discussed. Here, we report that the SMs [*surgical masks*] may be the potential sources of bacterial contamination with the progression of surgical procedure…

In summary, the topic of SMs in the OR has been controversial. The scientific study to support the OR policies surrounding this topic is marginal. The purpose of this study was to investigate whether the SMs is a potential source of bacterial shedding, which may lead to the understanding of the causes of SSI [*surgical site infection*]. Based on our research, we mainly draw three conclusions: (1) **SMs could be the source of bacterial shedding with extended wearing time**; thus, we recommend that surgeons must change his/her mask in every operation interval [*emphasis added*]..."

[137] **ADDED since 2/8/2022**
Facemask versus No Facemask in Preventing Viral Respiratory Infections During Hajj: A Cluster Randomised Open Label Trial
The Lancet — National Centre for Immunisation Research and Surveillance, Australia
Mohammad Alfelali, Elizabeth Ann Haworth, *et al*.
March 11, 2019
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3349234

"**Background**: This large-scale cluster-randomised controlled trial (cRCT) evaluated use of facemasks against laboratory-confirmed viral respiratory tract infections (vRTIs) and clinical respiratory infection (CRI) because previous studies have been inconclusive.

Methods: An open label cRCT, conducted in Makkah compared the offer and use of 50 surgical facemasks worn over five days versus no facemasks among pilgrims… Clinical and laboratory data were analysed for facemask efficacy against laboratory-confirmed vRTIs and CRI…

Findings: From October 13 to 17 in 2013, October 2 to 6 in 2014, and September 22 to 26 in 2015, 7,687 adult participants from 318 tents were randomised to facemasks or no facemasks; 3,864 participants from 149 tents were assigned to the Facemask group and 3,823 participants from 169 tents to the Control group. In the Facemask arm, respectively 27% and 51% participants used facemasks daily and intermittently, 22% did not; in the Control arm, respectively 15% and 38% participants used facemasks daily and intermittently, 47% did not. Respiratory viruses were detected in 277 of 650 (43%) nasal/pharyngeal swabs from symptomatic pilgrims. In intention-to-treat analysis, facemask use was neither effective against laboratory-confirmed vRTIs (OR 1.35, 95% CI 0.88-2.07) nor against CRI (OR 1.1, 95% CI 0.88-1.39), not even in per-protocol analysis (OR 1.2, 95% CI 0.87-1.69; OR 1.3, 95% CI 0.99-1.83).

Interpretation: Facemask use **does not prevent** clinical or laboratory-confirmed viral respiratory infections among Hajj pilgrims."

[138] ***Surgical masks as source of bacterial contamination during operative procedures***
Journal of Orthopaedic Translation
Liu Zhiqing, Chang Yongyun, *et al*.
July 2018
https://www.sciencedirect.com/science/article/pii/S2214031X18300809

"This study provides strong evidence for the identification that SMs [*surgical masks*] as source of bacterial contamination during operative procedures, which should be a cause for alarm and attention in the prevention of surgical site infection in clinical practice."

[139] ***Effect of a surgical mask on six minute walking distance***
Revue des Maladies Respiratoires
E. Person, C. Lemercier, *et al*.
March 2018
https://pubmed.ncbi.nlm.nih.gov/29395560/

"**Aim of the study**: To evaluate the effect of wearing a surgical mask during 6MWT in healthy subjects.

Results: Distance was not modified by the mask (P=0.99). Dyspnea [*shortness of breath or breathlessness*] variation was significantly higher with surgical mask (+5.6 vs. +4.6; P<0.001) and the difference was clinically relevant. No difference was found for the variation of other parameters.

Conclusion: Wearing a surgical mask modifies significantly and clinically dyspnea without influencing walked distance."

[140] ***A cluster randomised trial of cloth masks compared with medical masks in healthcare workers***
British Medical Journal — University of New South Wales, Australia
C. Raina MacIntyre, Holly Seale, *et al*.
March 26, 2015
https://bmjopen.bmj.com/content/5/4/e006577

"**Objective**: The aim of this study was to compare the efficacy of cloth masks to medical masks in hospital healthcare workers (HCWs). The null hypothesis is that there is no difference between medical masks and cloth masks.

Main outcome measure: Clinical respiratory illness (CRI), influenza-like illness (ILI) and laboratory-confirmed respiratory virus infection.

Results: The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%.

Conclusions: This study is the first RCT of cloth masks, and **the results caution against the use of cloth masks**. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection. Further research is needed to inform the widespread use of cloth masks globally. However, as a precautionary measure, cloth masks should not be recommended for HCWs, particularly in high-risk situations, and guidelines need to be updated."

[141] **ADDED since 2/8/2022**
Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: A randomized controlled trial
American Journal of Infection Control — St. Luke's Life Science Institute Center for Clinical Epidemiology, Japan
Joshua L. Jacobs, Sachiko Ohde, *et al*.
June 1, 2009
https://www.ajicjournal.org/article/S0196-6553(08)00909-7/fulltext

"**Background**: Health care workers outside surgical suites in Asia use surgical-type face masks commonly. Prevention of upper respiratory infection is one reason given, although evidence of effectiveness is lacking…

Conclusion: Face mask use in health care workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds."

Bioethics, Human Rights, and Informed Consent

International Law

[142] ***The Nuremberg Code***
August 1947
http://www.cirp.org/library/ethics/nuremberg/

[143] ***International Covenant on Civil and Political Rights***
December 16, 1966
https://www.ohchr.org/EN/ProfessionalInterest/Pages/CCPR.aspx

> "**Article 7**. No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."

[144] ***Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction***
Bureau of International Security and Nonproliferation
March 26, 1975
https://2009-2017.state.gov/t/isn/4718.htm

> "Have agreed as follows:
>
> **Article I**
>
> Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
>
> (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
>
> (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict."

[145] ***Universal Declaration on Bioethics and Human Rights***
October 19, 2005
http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

> "**Article 3 – Human dignity and human rights**:
>
> 1. Human dignity, human rights and fundamental freedoms are to be fully respected.
>
> 2. The interests and welfare of the individual should have priority over the sole interest of science or society."

"**Article 4 – Benefit and harm**: In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized."

"**Article 6 – Consent**

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent."

[146] ***White Paper: Civil Liberties surrounding Medical Experimentation***
America's Frontline Doctors
https://americasfrontlinedoctors.org/wp-content/uploads/2021/06/NEW-Civil-Liberties-Human-Rights-Issues-Surrounding-the-COVID-19-Vaccine-Candidates7.36.22-PM-min.pdf

"For many decades it has been illegal and unethical to mandate or coerce any medical treatment. Virtually all countries, NGOs, organizations, policy leaders, and physicians adhere to this principle, including the USA, the European Union, United Nations and the World Health Organization. Quite simply, by international law, no person can ever be coerced to take an experimental treatment. Unfortunately, AFLDS is aware of many people who have already been fired for refusing to take what is currently an experimental medication. This paper addresses this issue."

US Law

[147] ***21 U.S. Code § 360bbb–3 - Authorization for medical products for use in emergencies***
https://www.law.cornell.edu/uscode/text/21/360bbb-3

> "(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed … (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

[148] **Electronic Code of Federal Regulations: *45 CFR § 46.116 - General requirements for informed consent*.**
https://www.law.cornell.edu/cfr/text/45/46.116

> "**(a) General**. General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section…
>
> (2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence…
>
> (4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
>
> (5) Except for broad consent obtained in accordance with paragraph (d) of this section:
>
> (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
>
> (6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
>
> **(b) Basic elements of informed consent**. … [I]n seeking informed consent the following information shall be provided to each subject or the legally authorized representative:..
>
> (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject."

Professional Medical Codes

[149] ***World Medical Association Declaration of Geneva***
Adopted September 1948 and last amended October 2017
https://www.wma.net/policies-post/wma-declaration-of-geneva/

"**The Physician's Pledge**

As a member of the medical profession:

I solemnly pledge to dedicate my life to the service of humanity;

The health and well-being of my patient will be my first consideration;

I will respect the autonomy and dignity of my patient;

I will maintain the utmost respect for human life; …

I will not use my medical knowledge to violate human rights and civil liberties, even under threat"

[150] ***Declaration of Helsinki***
World Medical Association
June 1964
https://apps.who.int/iris/bitstream/handle/10665/268312/PMC2566407.pdf?sequence=1&isAllowed=y

"**B. Basic principles for all medical research** …

20. The subjects must be volunteers and informed participants in the research project.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship."

[151] ***Physicians Declaration – Global COVID Summit, Rome, Italy***
International Alliance of Physicians and Medical Scientists
September 2021
https://doctorsandscientistsdeclaration.org/

"**Update**: as of 8am ET on 1/18/22 over 17,000 doctors & scientists have signed the Rome Declaration.

We the physicians of the world, united and loyal to the Hippocratic Oath, recognizing the profession of medicine as we know it is at a crossroad, are compelled to declare the following; …

WHEREAS, there is an unprecedented assault on our ability to care for our patients;

WHEREAS, public policy makers have chosen to force a 'one size fits all' treatment strategy, resulting in needless illness and death, rather than upholding fundamental concepts of the individualized, personalized approach to patient care which is proven to be safe and more effective; …

WHEREAS, physicians are increasingly being discouraged from engaging in open professional discourse and the exchange of ideas about new and emerging diseases, not only endangering the essence of the medical profession, but more importantly, more tragically, the lives of our patients;

WHEREAS, thousands of physicians are being prevented from providing treatment to their patients, as a result of barriers put up by pharmacies, hospitals, and public health agencies, rendering the vast majority of healthcare providers helpless to protect their patients in the face of disease. Physicians are now advising their patients to simply go home (allowing the virus to replicate) and return when their disease worsens, resulting in hundreds of thousands of unnecessary patient deaths, due to failure-to-treat;

WHEREAS, this is not medicine. This is not care. These policies may actually constitute crimes against humanity.

NOW THEREFORE, IT IS:

RESOLVED, that the physician-patient relationship must be restored. The very heart of medicine is this relationship, which allows physicians to best understand their patients and their illnesses, to formulate treatments that give the best chance for success, while the patient is an active participant in their care.

RESOLVED, that the political intrusion into the practice of medicine and the physician/patient relationship must end. Physicians, and all health care providers, must be free to practice the art and science of medicine without fear of retribution, censorship, slander, or disciplinary action… More than ever, the right and ability to exchange objective scientific findings, which further our understanding of disease, must be protected.

RESOLVED, that physicians must defend their right to prescribe treatment, observing the tenet FIRST, DO NO HARM. Physicians shall not be restricted from prescribing safe and effective treatments. These restrictions continue to cause unnecessary sickness and death. The rights of patients, after being fully informed about the risks and benefits of each option, must be restored to receive those treatments…

RESOLVED, that we invite the scientists of the world, who are skilled in biomedical research and uphold the highest ethical and moral standards, to insist on their ability to conduct and publish objective, empirical research without fear of reprisal upon their careers, reputations and livelihoods…

IN WITNESS WHEREOF, the undersigned has signed this Declaration as of the date first written."

COVID-19 Statistics

Infection Fatality Rate (IFR) for COVID-19

Note: The citations below are presented in reverse, chronological order.

[152] **ADDED since 2/8/2022**
Age-stratified infection fatality rate of COVID-19 in the non-elderly population
Environmental Research — Stanford University
Angelo Maria Pezzullo, Cathrine Axfors, Despina G. Contoupolis-Ioannidis, Alexandre Apostoloatos, and John P.A. Ioannidis
January 1, 2023
https://www.sciencedirect.com/science/article/pii/S001393512201982X

"**Highlights**

- Across 31 systematically identified national seroprevalence studies in the pre-vaccination era, the median infection fatality rate of COVID-19 was estimated to be **0.034% for people aged 0–59 years** and **0.095% for those aged 0–69 years**.
- The median IFR was 0.0003% at 0–19 years, 0.002% at 20–29 years, 0.011% at 30–39 years, 0.035% at 40–49 years, 0.123% at 50–59 years, and 0.506% at 60–69 years.
- At a global level, pre-vaccination IFR may have been as low as 0.03% and 0.07% for 0–59 and 0–69 year old people, respectively.
- These IFR estimates in non-elderly populations are lower than previous calculations had suggested."

[153] **UPDATED since 2/8/2022**
#Studies on COVID-19 Lethality
Swiss Policy Research
Updated September 2022
https://swprs.org/studies-on-covid-19-lethality/

Note: For a list of IFRs by country, see the Table under '1. Antibody studies.'

"In most Western countries, the median age of covid deaths is 80+ years and about 50% of deaths occurred in care homes…

By the end of March 2021, there were close to 3 million covid deaths in close to 8 billion people. At a global infection attack rate of 10% to 30%, this results in an average global covid lethality (IFR) of **0.1%** to **0.35%** and a global covid mortality of about 0.035%. By comparison, the 1918 flu pandemic had a global mortality of about 2.3% (40 million deaths in 1.8 billion people).

For comparison, the IFR of seasonal influenza, against which prior immunity and vaccines exist, is about 0.05% to 0.1%."

[154] **ADDED since 2/8/2022**

Tweet by Rochelle Walensky, director of the Centers for Disease Control and Prevention
June 24, 2021
https://twitter.com/CDCDirector/status/1408116464683569157

> "To put this into perspective, if we vaccinate 1 million 12-17 year olds, we could see 30-40 MILD cases of myocarditis. In this same 1 million, through vaccination we AVOID: 8,000 cases of COVID-19, 200 hospitalizations, 50 ICU stays & **1 death**. The benefits far outweigh the risks."

[155] ***Reconciling estimates of global spread and infection fatality rates of COVID-19: An overview of systematic evaluations***
European Journal of Clinical Investigation
John P A Ioannidis
March 26, 2021
https://onlinelibrary.wiley.com/doi/10.1111/eci.13554

> "**Conclusions**: … Acknowledging residual uncertainties, the available evidence suggests average global IFR of **~0.15%** and ~1.5-2.0 billion infections by February 2021 with substantial differences in IFR and in infection spread across continents, countries and locations."

[156] **ADDED since 2/8/2020**

COVID-19 Pandemic Planning Scenarios
Centers for Disease Control and Prevention
March 19, 2021
https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html

Best estimates of infection fatality ratios:

0-17 years old = **0.002%** [(20 / 1,000,000) * 100]

18-49 years old = **0.05%** [(500 / 1,000,000) * 100]

50-64 years old = **0.06%** [(6,000 / 1,000,000) * 100]

65+ years old = 9.0% [(90,000 / 1,000,000) * 100]

Table 1. Parameter Values that vary among the five COVID-19 Pandemic Planning Scenarios. The scenarios are intended to advance public health preparedness and planning. They are **not** predictions or estimates of the expected impact of COVID-19.

Parameter	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5: Current Best Estimate
R_0*	2.0		4.0		2.5
Infection fatality ratio (Estimated number of deaths per 1,000,000 infections)†	0–17 years old: 6 18–49 years old: 150 50–64 years old: 1,800 65+ years old: 26,000		0–17 years old: 80 18–49 years old: 1,700 50–64 years old: 20,000 65+ years old: 270,000		0–17 years old: 20 18–49 years old: 500 50–64 years old: 6,000 65+ years old: 90,000

[157] ***Infection fatality rate of COVID-19 inferred from seroprevalence data***
World Health Organization
John P A Ioannidis
October 14, 2020
https://www.who.int/bulletin/online_first/BLT.20.265892.pdf

> "**Results**: … Across 51 locations, the median COVID-19 infection fatality rate was 0.27% (corrected **0.23%**)"

[158] ***Global perspective of COVID-19 epidemiology for a full-cycle pandemic***
European Journal of Clinical Investigation
John P A Ioannidis
October 7, 2020
https://onlinelibrary.wiley.com/doi/10.1111/eci.13423

> "**Abstract**: … Global infection fatality rate is **0.15-0.20%** (0.03-0.04% in those <70 years), with large variability across locations with different age-structure, institutionalization rates, socioeconomic inequalities, population-level clinical risk profile, public health measures, and health care."

[159] ***Estimating the infection fatality ratio in England***
Centre for Evidence-Based Medicine
Daniel Howdon, Jason Oke, and Carl Heneghan
August 21, 2020
https://www.cebm.net/covid-19/estimating-the-infection-fatality-ratio-in-england/

> "**Summary**: This article presents data from two models estimating daily infections in England, deriving recent IFRs estimates of **0.30%** using the MRC unit's data and **0.49%** using ONS data."

[160] ***Serology-informed estimates of SARS-CoV-2 infection fatality risk in Geneva, Switzerland***
The Lancet
Javier Perez-Saez, Stephen A. Lauer, *et al*.
July 14, 2020
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30584-3/fulltext

> "After accounting for demography and age-specific seroprevalence, we estimated a population-wide IFR of 0·64% [***0-0.64%***]"

[161] **ADDED since 2/8/2020**

WHO Director-General's opening remarks at the media briefing on COVID-19
World Health Organization
March 3, 2020
https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---3-march-2020
See also ***WHO says coronavirus death rate is 3.4% globally, higher than previously thought***
https://www.cnbc.com/2020/03/03/who-says-coronavirus-death-rate-is-3point4percent-globally-higher-than-previously-thought.html

> "Globally, about **3.4%** of reported COVID-19 cases have died. By comparison, seasonal flu generally kills far fewer than 1% of those infected."

[162] **ADDED since 2/8/2020**

Covid-19 — Navigating the Uncharted
New England Journal of Medicine
Anthony Fauci
March 26, 2020
https://www.nejm.org/doi/full/10.1056/NEJMe2002387

> "On the basis of a case definition requiring a diagnosis of pneumonia, the currently reported case fatality rate is approximately 2%."

At-risk Demographics for COVID-19

Demographic: Existing Conditions

[163] **UPDATED since 2/8/2022**
#Weekly Updates by Select Demographic and Geographic Characteristics - Provisional Death Counts for Coronavirus Disease 2019 (COVID-19)
Centers for Disease Control and Prevention
Data as of April 2, 2023
https://www.cdc.gov/nchs/nvss/vsrr/COVID_weekly/index.htm#Comorbidities

> "**Comorbidities and other conditions**. Table 3 shows the types of health conditions and contributing causes mentioned in conjunction with deaths involving coronavirus disease 2019 (COVID-19). The number of deaths that mention one or more of the conditions indicated is shown for all deaths involving COVID-19 and by age groups. For over **5% of these deaths**, COVID-19 was the only cause mentioned on the death certificate. For deaths with conditions or causes in addition to COVID-19, on average, there were **4.0 additional conditions** or causes per death [*emphasis added*]."

Note: The citations below are presented in reverse, chronological order.

[164] **ADDED since 2/8/2022**
Lost microbes of COVID-19: Bifidobacterium, Faecalibacterium depletion and decreased microbiome diversity associated with SARS-CoV-2 infection severity
BMJ Open Gastroenterology — ProgenaBiome LLC
Sabine Hazan, Neil Stollman, *et al*.
April 28, 2022
https://bmjopengastro.bmj.com/content/9/1/e000871

> "**Objective**: The study objective was to compare gut microbiome diversity and composition in SARS-CoV-2 PCR-positive patients whose symptoms ranged from asymptomatic to severe versus PCR-negative exposed controls.
>
> **Results**: Compared with controls (n=20), severely symptomatic SARS-CoV-2-infected patients (n=28) had **significantly less bacterial diversity** (Shannon Index, p=0.0499; Simpson Index, p=0.0581), and positive patients overall had **lower relative abundances** of Bifidobacterium (p<0.0001), Faecalibacterium (p=0.0077) and Roseburium (p=0.0327), while having increased Bacteroides (p=0.0075). Interestingly, there was an inverse association between disease severity and abundance of the same bacteria.
>
> **Conclusion**: We hypothesise that low bacterial diversity and depletion of Bifidobacterium genera either before or after infection led to reduced proimmune function, thereby allowing SARS-CoV-2 infection to become symptomatic. This particular dysbiosis pattern may be a susceptibility marker for symptomatic severity from SARS-CoV-2 infection and may be amenable to preinfection, intrainfection or postinfection intervention."

[165] **Freedom of Information (FOI) request: *COVID-19 deaths and autopsies Feb 2020 to Dec 2021***
Office for National Statistics (UK)
January 17, 2022
https://www.ons.gov.uk/aboutus/transparencyandgovernance/freedomofinformationfoi/covid19deathsandautopsiesfeb2020todec2021

"**You asked**: Please supply deaths caused solely by covid 19, where covid is the only cause of death listed on the death certificate, broken down by age group and gender between feb 2020 up to and including dec 2021.

Please supply the number of autopsies carried out on those where covid was the only cause stated…

We said: … We do not hold analysis on the number of post-mortems completed."

Table 1: Number of deaths where COVID-19 was the only cause mentioned on the death certificate, 1 February 2020 to 31 December 2021, by sex and age group, England and Wales

Age group	Males	Females
<1	1	0
1-4	0	0
5-9	0	0
10-14	0	1
15-19	1	0
20-24	4	1
25-29	12	3
30-34	24	7
35-39	42	15
40-44	52	24
45-49	87	43
50-54	138	52
55-59	234	92
60-64	254	102
65-69	279	119
70-74	357	204
75-79	395	252

[166] ***Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021***
CDC Preventing Chronic Disease
Lyudmyla Kompaniyets, Audrey F. Pennington, *et al*.
July 2021
https://www.cdc.gov/pcd/issues/2021/pdf/21_0123.pdf

> "**Results**: Among 4,899,447 hospitalized adults… 540,667 (11.0%) were patients with COVID-19, of whom 94.9% had at least 1 underlying medical condition. Essential hypertension (50.4%), disorders of lipid metabolism (49.4%), and obesity (33.0%) were the most common. **The strongest risk factors for death were obesity** (adjusted risk ratio [aRR] = 1.30; 95% CI, 1.27–1.33), **anxiety and fear-related disorders** (aRR = 1.28; 95% CI, 1.25–1.31), **and diabetes with complication** (aRR = 1.26; 95% CI, 1.24–1.28), **as well as the total number of conditions** [*emphasis added*]."

[167] **Video (3m): *CDC director responds to criticisms on COVID-19 guidance***
January 7, 2021
https://www.youtube.com/watch?v=BhOoWGXRGb0&t=152s

> **Rochelle Walensky, CDC Director**: "The overwhelming number of deaths, **over 75%**, occurred in people who had **at least 4 co-morbidities** [*emphasis added*]. So really these are people who were unwell to begin with."

[168] ***Deaths involving COVID-19, England and Wales***
UK Office for National Statistics
June 2020 edition
Note: This is the last dataset produced in this series.
https://www.ons.gov.uk/file?uri=%2fpeoplepopulationandcommunity%2fbirthsdeathsandmarriages%2fdeaths%2fdatasets%2fdeathsinvolvingcovid19englandandwales%2fjune2020/referencetables.xlsx

> "These data tables contain detailed analysis of all deaths that occurred in England and Wales between 1 March and 30 June 2020, registered up to 4 July 2020, where the coronavirus (COVID-19) was involved. There are breakdowns by age and sex and the causes of death mentioned on the death certificate."
>
> **Note**: As indicated by the death certificates for this period, **91.3%** [(47,809 – 4,169) / 47,809] **of all COVID-related fatalities had one or more pre-existing conditions** [*emphasis added*], as calculated from the figures below.
>
> **Table 6b:** Number of deaths involving COVID-19 by main pre-existing condition, sex and age, England, deaths occurring between March and June 2020

4,169 deaths with “No pre-existing conditions” – Sum of:

- 95 deaths, Age 0-44
- 89 deaths, Age 45-49
- 111 deaths, Age 50-54
- 209 deaths, Age 55-59
- 215 deaths, Age 60-64
- 278 deaths, Age 65-69
- 370 deaths, Age 70-74
- 485 deaths, Age 75-79
- 654 deaths, Age 80-84
- 753 deaths, Age 85-89
- 910 deaths, Age 90+

47,809 “All deaths involving COVID-19” – Sum of:

- 517 deaths, Age 0-44
- 441 deaths, Age 45-49
- 803 deaths, Age 50-54
- 1,375 deaths, Age 55-59
- 1,970 deaths, Age 60-64
- 2,629 deaths, Age 65-69
- 4,368 deaths, Age 70-74
- 6,351 deaths, Age 75-79
- 9,137 deaths, Age 80-84
- 9.808 deaths, Age 85-89
- 10,410 deaths, Age 90+

[169] **ADDED since 2/8/2022**

Italy Says 96% of Virus Fatalities Suffered From Other Illnesses

Bloomberg

Tommaso Ebhardt & Marco Bertacche

May 26, 2020

https://archive.ph/20200529022809/https://www.bloomberg.com/news/articles/2020-05-26/italy-says-96-of-virus-fatalities-suffered-from-other-illnesses#selection-2381.0-2381.64

> "The coronavirus outbreak in Italy has struck overwhelmingly among the nation's older population and those with preexisting medical conditions, according to the national health authority.
>
> Almost **96%** of the **country's virus fatalities had previous medical conditions**, data from Italy's ISS health institute show. The ISS, which publishes a range of studies on the outbreak including a detailed weekly report, confirms a trend seen since the beginning of the emergency, with the **average age of Italians** who've died from the virus at around **80**.
>
> 'The latest numbers show that new cases and fatalities have a common profile: mostly elderly people with previous illnesses,' ISS chief Silvio Brusaferro said at a news conference Friday."

[170] ***Nearly 90% of People Hospitalized for COVID-19 Have Underlying Conditions, Says CDC***

Health magazine

Amber Brenza

April 9, 2020

https://www.health.com/condition/infectious-diseases/coronavirus/covid-19-hospitalization

> "In a new study published for the CDC's Morbidity and Mortality Weekly Report, researchers found that the majority of those hospitalized due to COVID-19 have preexisting conditions—about 90% of patients with available data had one or more underlying conditions. The most common, per the CDC, include hypertension (49.7%), obesity (48.3%), chronic lung disease (34.6%), diabetes mellitus (28.3%), and cardiovascular disease (27.8%)."

Demographic: Age

[171] ***COVID-19 confirmed deaths in England r(to 31 January 2021): report***
UK Health Security Agency
Updated May 3, 2022
https://www.gov.uk/government/publications/covid-19-reported-sars-cov-2-deaths-in-england/covid-19-confirmed-deaths-in-england-report

Table 2. Number of deaths and mortality rate (per 100,000 population) in laboratory-confirmed cases of COVID-19, by age group†**

Age group	Deaths (week 27 onwards*)	Mortality rate** (95% CI) (week 27 onwards*)	Deaths (January 2021)	Mortality rate** (95% CI) (January 2021)
<5	<10	0.3 (0.1-0.6)	<10	0.7 (0.1-2.6)
5-9	<10	0.1 (0.0-0.4)	<10	0.3 (0.0-1.9)
10-19	18	0.5 (0.3-0.7)	<10	0.9 (0.3-2.1)
20-29	89	2.1 (1.7-2.5)	39	6.3 (4.5-8.6)
30-39	331	7.4 (6.6-8.3)	185	28.9 (24.9-33.4)
40-49	962	22.8 (21.4-24.3)	507	83.7 (76.6-91.3)
50-59	2,955	65.9 (63.5-68.3)	1,574	244.6 (232.6-256.9)
60-69	6,746	192.9 (188.4-197.6)	3,354	668.4 (645.9-691.4)
70-79	15,473	553.9 (545.3-562.7)	7,231	1,803.8 (1,762.5-1,845.9)
80+	39,897	2,376.4 (2,353.2-2,399.9)	18,931	7,856.9 (7,745.4-7,969.6)

*Data is presented from 29 June 2020 to 31 January 2021.

[172] **UPDATED since 2/8/2022**
#Studies on Covid-19 Lethality - Median age of Covid-19 deaths per country
Swiss Policy Research
Published May 2020, updated September 2022
https://swprs.org/studies-on-covid-19-lethality/#age

Half of all deaths were below, half were above the median age.

Country	Median age	Source
Australia	82 years	DOH
Austria	82 years	EMS
Belgium	86 years	IBS
Brazil	70 years	MDX
Canada	86 years	HCSC
England	82 years	NHS
France	84 years	SPF
Germany	83 years	RKI
Italy	82 years	ISS
South Africa	62 years	SAC
Spain	82 years	MDS
Sweden	84 years	FOHM
Switzerland	86 years	BAG
USA	78 years	CDC

Note: The citations below are presented in reverse, chronological order.

[173] **ADDED since 2/8/2022**
Independent report: JCVI statement on vaccination of children aged 5 to 11 years old
Department of Health & Social Care, UK
Joint Committee on Vaccination and Immunisation (JCVI)
February 16, 2022

https://www.gov.uk/government/publications/jcvi-update-on-advice-for-covid-19-vaccination-of-children-aged-5-to-11/jcvi-statement-on-vaccination-of-children-aged-5-to-11-years-old

Note: According to Table 1 of this report, to prevent a single hospitalization in children aged 5-11 due to acute COVID-19, it would require the administration of 10,300-58,000 vaccination doses. Similarly, 340,000-1,900,000 doses would need to be administered to prevent a single ICU admission due to acute COVID-19. See Table

Table 1 - Prevented cases in 5 to 11 year olds, per million vaccine courses and number needed to vaccinate to prevent one case

Scenario	Measure	PIMS-TS (hospitalisations/ ICU admissions)	Hospitalisations due to acute COVID-19	ICU admissions due to acute COVID-19
More severe future wave*	Prevented per million courses of 2 doses	58	98	3.0
More severe future wave*	Number needed to vaccinate to prevent 1 case	17,000	10,300	340,000
Less severe future wave**	Prevented per million courses of 2 doses	10	17	0.5
Less severe future wave**	Number needed to vaccinate to prevent 1 case	95,000	58,000	1,900,000

*More severe: may be a wave due to a variant with disease severity similar to a pre-Omicron variant; in a population with a lower level of natural immunity provided by previous infection.

**Less severe: may be a wave due to a variant with disease severity similar to Omicron; in a population with a higher level of natural immunity provided by previous infection.

[174] ***Risk of Hospitalization, severe disease, and mortality due to COVID-19 and PIMS-TS in children with SARS -CoV-2 infection in Germany***
Ludwig Maximilians-University Munich and Technische Universität Dresden (Germany)
A.L. Sorg, M. Hufnagel, *et al*.
November 30, 2021
https://www.medrxiv.org/content/10.1101/2021.11.30.21267048v1.full.pdf

"**Results**: While the overall hospitalization rate associated with SARS-CoV-2 infection was 35.9 per 10,000 children, ICU admission rate was **1.7 per 10,000** and case fatality was **0.09 per 10,000** [*emphasis added*]. Children without comorbidities were found to be significantly less likely to suffer from a severe or fatal disease course. The lowest risk was observed in children aged 5-11 without comorbidities. In this group, the ICU admission rate was 0.2 per 10,000 and case fatality could not be calculated, due to an absence of cases."

[175] ***Immunocompromised children and young people are at no increased risk of severe COVID-19***
Journal of Infection (University of Southampton and University of Nottingham)
H. Chappell, R. Patel, *et al*.
November 14, 2021
https://www.sciencedirect.com/science/article/pii/S016344532100548X

"**Methods**: From March 2020 to 2021 weekly questionnaires were sent to immunocompromised paediatric patients or their parents. Information, including symptom presentation and SARS-CoV-2 PCR test results, was collected from 1527 participants from 46 hospitals.

Conclusions: This study shows SARS-CoV-2 infections have occurred in immunocompromised children and young people with no increased risk of severe disease. No children died."

[176] ***Physicians Declaration II***
International Alliance of Physicians and Medical Scientists (Global Covid Summit)
October 29, 2021
https://doctorsandscientistsdeclaration.org/

For excerpts, see [377].

[177] ***Why are we vaccinating children against COVID-19?***
Toxicology Reports
Ronald N. Kostoff, Daniela Calina, *et al*.
October 7, 2021
https://www.sciencedirect.com/science/article/pii/S221475002100161X

"**Abstract**: This article examines issues related to COVID-19 inoculations for children. The bulk of the official COVID-19-attributed deaths per capita occur in the elderly with high comorbidities, and the COVID-19 attributed deaths per capita are negligible in children. The bulk of the normalized post-inoculation deaths also occur in the elderly with high comorbidities, while the normalized post-inoculation deaths are small, but not negligible, in children. Clinical trials for these inoculations were very short-term (a few months), had samples not representative of the total population, and for adolescents/children, had poor predictive power

because of their small size. Further, the clinical trials did not address changes in biomarkers that could serve as early warning indicators of elevated predisposition to serious diseases. Most importantly, the clinical trials did not address long-term effects that, if serious, would be borne by children/adolescents for potentially decades.

A novel best-case scenario cost-benefit analysis showed very conservatively that **there are five times the number of deaths attributable to each inoculation vs those attributable to COVID-19 in the most vulnerable 65+ demographic** [*emphasis added*]. The risk of death from COVID-19 decreases drastically as age decreases, and the longer-term effects of the inoculations on lower age groups will increase their risk-benefit ratio, perhaps substantially…

Discussion: … [W]here is the data justifying inoculation for children, much less most people under forty? It's not found on Fig. 1, where the most vulnerable are almost exclusively the elderly with many comorbidities…

What is the rush for a group at essentially zero risks? Given that the inoculations were tested only for a few months, only very short-term adverse effects could be obtained. It is questionable how well even these short-term effects obtained from the clinical trials reflect the short-term effects from the initial mass inoculation results reported in VAERS.

Fig. 1, Fig. 2 reflect only these very short-term results. A number of researchers have suggested the possibility of severe longer-term autoimmune, Antibody-Dependent Enhancement, neurological, and other potentially serious effects, with **lag periods ranging from months to years**. If such effects do turn out to be real, the children are the ones who will have to bear the brunt of the suffering [*emphasis added*]."

[178] ***The Flimsy Evidence Behind the CDC's Push to Vaccinate Children***
Wall Street Journal
Marty Makary, Johns Hopkins University School of Medicine
July 19, 2021
https://web.archive.org/web/20210801202627/https://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868

"A tremendous number of government and private policies affecting kids are based on one number: 335. That is how many children under 18 have died with a Covid diagnosis code in their record, according to the Centers for Disease Control and Prevention. Yet the CDC, which has 21,000 employees, hasn't researched each death to find out whether Covid caused it or if it involved a pre-existing medical condition.

Without these data, the CDC Advisory Committee on Immunization Practices decided in May that the benefits of two-dose vaccination outweigh the risks for all kids 12 to 15. I've written hundreds of peer-reviewed medical studies, and I can think of no journal editor who would accept the claim that 335 deaths resulted from a virus **without data to indicate if the virus was incidental or causal**, and without an analysis of relevant risk factors such as obesity [*emphasis added*].

My research team at Johns Hopkins worked with the nonprofit FAIR Health to analyze approximately 48,000 children under 18 diagnosed with Covid in health-insurance data from April to August 2020. Our report found a **mortality rate of zero** among children without a pre-existing medical condition such as leukemia [*emphasis added*]. If that trend holds, it has

significant implications for healthy kids and whether they need two vaccine doses."

[179] ***Deaths from COVID 'incredibly rare' among children***
Nature
Heidi Ledford
July 15, 2021
https://www.nature.com/articles/d41586-021-01897-w

"A comprehensive analysis of hospital admissions and reported deaths across England suggests that COVID-19 carries a lower risk of dying or requiring intensive care among children and young people than was previously thought.

In a series of preprints published on medRxiv, a team of researchers picked through all hospital admissions and deaths reported for people younger than 18 in England. The studies found that COVID-19 caused 25 deaths in that age group between March 2020 and February 2021.

About half of those deaths were in individuals with an underlying complex disability with high health-care needs, such as tube feeding or assistance with breathing."

[180] **ADDED since 2/8/2022**
A focused protection vaccination strategy: why we should not target children with COVID-19 vaccination policies
Journal of Medical Ethics
Alberto Giubilini, Sunetra Gupta, and Carl Heneghan
July 7, 2021
https://jme.bmj.com/content/47/8/565

"The risks of COVID-19 for children and young people are minimal. For example, '[i]n the USA, UK, Italy, Germany, Spain, France and South Korea, deaths from COVID-19 in children remained rare up to February 2021 (ie, up to the time the study had available data about), at 0.17 per 100 000 population'. The long-term risks of the novel COVID-19 vaccines on a population of millions of children are at the moment unknown, given that the clinical trials involved a few thousands of subjects over a few months period."

[181] ***Children and young people remain at low risk of COVID-19 mortality***
The Lancet – Child & Adolescent Health
Sunil S Bhopal, Jayshree Bagaria, Bayanne Olabi, and Raj Bhopal
March 10, 2021
https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(21)00066-3/fulltext

"In the USA, UK, Italy, Germany, Spain, France, and South Korea, deaths from COVID-19 in children remained rare up to February, 2021, at 0·17 per 100 000 population…"

[182] **Letter to the Editor: *Open Schools, Covid-19, and Child and Teacher Morbidity in Sweden***
New England Journal of Medicine
Jonas F. Ludvigsson, Lars Engerström, Charlotta Nordenhäll, and Emma Larsson
February 18, 2021
https://www.nejm.org/doi/10.1056/NEJMc2026670

> "We followed all children who were admitted to an ICU between March 1 and June 30, 2020 (school ended around June 10) with laboratory-verified or clinically verified Covid-19, including patients who were admitted for multisystem inflammatory syndrome in children (MIS-C, which is likely to be related to Covid-19) according to the Swedish Pediatric Rheumatology Quality Register… The Stockholm Ethics Review Board approved the study.
>
> The number of deaths from any cause among the 1,951,905 children in Sweden (as of December 31, 2019) who were 1 to 16 years of age was 65 during the pre–Covid-19 period of November 2019 through February 2020 and 69 during 4 months of exposure to Covid-19 (March through June 2020) (see the Supplementary Appendix). From March through June 2020, a total of 15 children with Covid-19 (including those with MIS-C) were admitted to an ICU (0.77 per 100,000 children in this age group) (Table 1), 4 of whom were 1 to 6 years of age (0.54 per 100,000) and 11 of whom were 7 to 16 years of age (0.90 per 100,000). Four of the children had an underlying chronic coexisting condition (cancer in 2, chronic kidney disease in 1, and hematologic disease in 1). **No child with Covid-19 died** [*emphasis added*]…
>
> Despite Sweden's having kept schools and preschools open, we found a low incidence of severe Covid-19 among schoolchildren and children of preschool age during the SARS-CoV-2 pandemic. Among the 1.95 million children who were 1 to 16 years of age, 15 children had Covid-19, MIS-C, or both conditions and were admitted to an ICU, which is equal to **1 child in 130,000** [*emphasis added*]."

[183] ***Statistics of the COVID-19 pandemic in the United States***
Wikipedia
February 17, 2021
https://en.wikipedia.org/wiki/Statistics_of_the_COVID-19_pandemic_in_the_United_States#Deaths_by_age
Note: In 2020 and early 2021, the CDC Web site presented data on the Infection Fatality Rates (IFR) by Age Group for COVID-19, and IFR is the best measurement to assess the risk of death for each age cohort. Although the CDC no longer appears to provide this information, the table below may serve as a proxy.

Provisional COVID-19 deaths in the United States by age as of February 17, 2021

Age group	Death count	% of deaths	Rate per 100,000
All ages	**460,234**	**100%**	**140.2**
Under 1y	45	<0.1%	1.2
1-4y	23	<0.1%	0.1
5-14y	72	<0.1%	0.2
15-24y	648	0.2%	1.5
25-34y	2,922	0.7%	6.4
35-44y	7,711	2%	18.5
45-54y	21,251	5%	60.0
55-64y	54,134	12%	127.5
65-74y	99,019	21%	314.5
75-84y	128,192	27%	802.7
85y and over	146,217	32%	2,213.7

[184] **ADDED since 2/8/2022**
Why is COVID-19 less severe in children? A review of the proposed mechanisms underlying the age-related difference in severity of SARS-CoV-2 infections
BMJ Archives of Disease in Childhood — Murdoch Children's Research Institute, Australia
Petra Zimmermann and Nigel Curtis
December 1, 2020
https://adc.bmj.com/content/106/5/429

"**Abstract**: In contrast to other respiratory viruses, children have less severe symptoms when infected with the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In this review, we discuss proposed hypotheses for the age-related difference in severity of coronavirus disease 2019 (COVID-19).

Factors proposed to explain the difference in severity of COVID-19 in children and adults include those that put adults at higher risk and those that protect children. The former include:

(1) age-related increase in endothelial damage and changes in clotting function; (2) higher density, increased affinity and different distribution of angiotensin converting enzyme 2 receptors and transmembrane serine protease 2; (3) pre-existing coronavirus antibodies (including antibody-dependent enhancement) and T cells; (4) immunosenescence and inflammaging, including the effects of chronic cytomegalovirus infection; (5) a higher prevalence of comorbidities associated with severe COVID-19 and (6) lower levels of vitamin D. Factors that might protect children include: (1) differences in innate and adaptive immunity; (2) more frequent recurrent and concurrent infections; (3) pre-existing immunity to coronaviruses; (4) differences in microbiota; (5) higher levels of melatonin; (6) protective off-target effects of live vaccines and (7) lower intensity of exposure to SARS-CoV-2."

[185] **ADDED since 2/8/2022**
8 in 10 People Who Have Died of COVID-19 Were Age 65 or Older – But the Share Varies By State
Kaiser Family Foundation
July 24, 2020
https://www.kff.org/coronavirus-covid-19/press-release/8-in-10-people-who-have-died-of-covid-19-were-age-65-or-older-but-the-share-varies-by-state/

"A new KFF analysis finds that 80 percent of people who have died of COVID-19 in the U.S. to date were age 65 or older."

[186] ***Covid-19 in schoolchildren: A comparison between Finland and Sweden***
Public Health Agency of Sweden
July 7, 2020
https://www.folkhalsomyndigheten.se/contentassets/c1b78bffbfde4a7899eb0d8ffdb57b09/covid-19-school-aged-children.pdf

"**Summary**: This report is a comparison between Finland and Sweden, two in many ways similar countries who applied different measures regarding schools during the covid-19 pandemic. There is no difference in the overall incidence of the laboratory confirmed covid-19 cases in the age group 1-19 years in the two countries… Severe covid-19 disease as measured in ICU admittance is very rare in both countries in this age group and **no deaths were reported** [*emphasis added*]…

In conclusion, closure or not of schools had no measurable direct impact on the number of laboratory confirmed cases in school-aged children in Finland or Sweden. The negative effects of closing schools must be weighed against the positive indirect effects it might have on the mitigation of the covid-19 pandemic."

[187] ***Characteristics and Outcomes of Children With Coronavirus Disease 2019 (COVID-19) Infection Admitted to US and Canadian Pediatric Intensive Care Units***
JAMA Pediatrics
Lara S. Shekerdemian, Nabihah R. Mahmood, *et al*.
May 11, 2020
https://jamanetwork.com/journals/jamapediatrics/fullarticle/2766037

"[U]p to this time of the pandemic in North America, children continue to face a far greater risk of critical illness from influenza than from COVID-19, pointing to the imperative for ongoing

preventive pediatric health maintenance during this time."

Demographic: Body Mass / Obesity

Note: The citations below are presented in reverse, chronological order.

[188] ***Characteristics and Clinical Outcomes of Children and Adolescents Aged <18 Years Hospitalized with COVID-19 — Six Hospitals, United States, July–August 2021***
Centers for Disease Control and Prevention (CDC)
Valentine Wanga, Megan E. Gerdes, *et al*.
December 31, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a3.htm?s_cid=mmmm705152a3_w

"Among the 713 patients hospitalized for COVID-19, 24.7% were aged <1 year, 17.1% were aged 1–4 years, 20.1% were aged 5–11 years, and 38.1% were aged 12–17 years. Approximately two thirds of patients (67.5%) had one or more underlying medical conditions, with obesity being the most common (32.4%)…

Among patients aged 12–17 years, **61.4 percent had obesity** (60.5 percent of whom had severe obesity) [*emphasis added*]…

Compared with patients without obesity, those with obesity required higher levels and longer duration of care. These findings are consistent with previous reports and highlight the importance of obesity and other medical conditions as risk factors for severe COVID-19 in children and adolescents."

[189] ***Impact of obesity on intensive care outcomes in patients with COVID-19 in Sweden—A cohort study***
PLOS ONE (University of Gothenburg, Sweden)
Lovisa Sjögren, Erik Stenberg, *et al*.
October 13, 2021
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0257891

"**Background**: Previous studies have shown that a high body mass index (BMI) is a risk factor for severe COVID-19. The aim of the present study was to assess whether a high BMI affects the risk of death or prolonged length of stay (LOS) in patients with COVID-19 during intensive care in Sweden.

Methods and findings: In this observational, register-based study, we included patients with COVID-19 from the Swedish Intensive Care Registry admitted to intensive care units (ICUs) in Sweden… We found a significant association between BMI and the risk of the composite outcome death or LOS ≥14 days in survivors (OR per standard deviation [SD] increase 1.30, 95%CI 1.16–1.44, adjusted for sex, age and comorbidities), and this association remained after further adjustment for severity of illness (simplified acute physiology score; SAPS3) at ICU admission (OR 1.30 per SD, 95%CI 1.17–1.45). Individuals with a BMI ≥ 35 kg/m2 had a doubled risk of the composite outcome. A high BMI was also associated with death during intensive care and a prolonged LOS in survivors assessed as separate outcomes…

Conclusions: In this large cohort of Swedish ICU patients with COVID-19, a high BMI was

associated with increasing risk of death and prolonged length of stay in the ICU…

Discussion: Previous studies, both observational and studies using the Mendelian randomization approach, have consistently found higher susceptibility and severity of the COVID-19 disease course in individuals with obesity. A UK study including almost 7 million individuals concluded increased risk of hospitalization and death due to COVID-19 in individuals with obesity… Another study that included over 17 million adults observed increased risk of COVID-19 related death with increasing obesity… Furthermore, one previous Swedish study found an increased risk of severe COVID-19 in patients with obesity with the most pronounced excess risk in individuals younger than 56 years of age… In the present study, using up-to-date BMI data, we found that a high BMI was associated with increased risk of death and prolonged intensive care in patients with severe COVID-19 after adjustment of age, sex and comorbidities..."

[190] ***Body Mass Index and Risk for COVID-19–Related Hospitalization, Intensive Care Unit Admission, Invasive Mechanical Ventilation, and Death — United States, March–December 2020***
CDC Morbidity and Mortality Weekly Report
Lyudmyla Kompaniyets, Alyson B. Goodman, *et al*.
March 8, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/mm7010e4.htm?s_cid=mm7010e4_w

"**What is added by this report?** Among 148,494 U.S. adults with COVID-19, a nonlinear relationship was found between body mass index (BMI) and COVID-19 severity, with lowest risks at BMIs near the threshold between healthy weight and overweight in most instances, then increasing with higher BMI. Overweight and obesity were risk factors for invasive mechanical ventilation. Obesity was a risk factor for hospitalization and death, particularly among adults aged <65 years…

A J-shaped (nonlinear) relationship was observed between continuous BMI and risk for three outcomes. Risk for hospitalization, ICU admission, and death were lowest at BMIs of 24.2 kg/m2, 25.9 kg/m2, and 23.7 kg/m2, respectively, and then **increased sharply with higher BMIs** [*emphasis added*] (Figure 2)… Estimated risks for hospitalization and death were consistently higher for older age groups; however, within each age group, risk increased with higher BMIs.

Discussion: … The findings in this report are similar to those from previous studies that indicate an increased risk for severe COVID-19–associated illness among persons with excess weight and provide additional information about a dose-response relationship between higher BMI and risk for hospitalization, ICU admission, invasive mechanical ventilation, and death."

[191] ***Covid-19 death rates 10 times higher in countries where most adults are overweight, report finds***
CNN Health
Lauren Mascarenhas and Zamira Rahim
March 5, 2021
https://www.cnn.com/2021/03/04/health/obesity-covid-death-rate-intl/index.html

> "The risk of death from Covid-19 is about 10 times higher in countries where most of the population is overweight, according to a report released Wednesday by the World Obesity Federation…
>
> The report found that every country where less than 40% of the population was overweight had a low Covid-19 death rate of **no more than 10 people per 100,000**…
>
> But in countries where more than 50% of the population was overweight, the Covid-19 death rate was much higher -- **more than 100 per 100,000** [*emphasis added*]…
>
> The research comes following multiple reports to date which suggest that being overweight or obese can increase the risk of dying from Covid-19. Being overweight is defined by having a Body Mass Index (BMI) of 25-29.9 kg/m², while obesity is defined as a BMI over 30 kg/m².
>
> A Public Health England report in July 2020 found that while having a higher body mass index (BMI) did not increase the chances of contracting Covid-19, it was linked to a greater risk of becoming seriously ill from the disease. One study found that for people with a BMI of 35 to 40, risk of death from COVID-19 increases by 40% and with a BMI over 40 by 90%."

[192] ***Excess Weight and COVID-19: Insights from new evidence***
Public Health England
Prepared by Jamie Blackshaw, Alison Feeley, *et al*.
July 2020
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/907966/PHE_insight_Excess_weight_and_COVID-19__FINAL.pdf

> "**Executive summary**: … Evidence on the links between weight status and COVID-19 outcomes are drawn primarily from three sources: retrospective cohort studies, clinical audits of patients with COVID-19 in hospital and routine primary care records with data linkage to outcomes. This evidence suggests excess weight is associated with an increased risk of the following for COVID-19: a positive test, hospitalisation, advanced levels of treatment (including mechanical ventilation or admission to intensive or critical care) and death. The risks seem to increase progressively with increasing BMI above the healthy weight range, even after adjustment for potential confounding factors, including demographic and socio-economic factors…
>
> **Hospitalization**: … Hamer et al reported that, compared with patients with BMI <25kg/m2, those living with overweight or obesity had an increased risk of hospitalisation, RR 1.32 and 1.97 respectively (after adjusting for age, sex, education, ethnicity, diabetes, hypertension, cardiovascular disease).

In New York, Petrilli et al reported that people living with obesity (BMI 30-39.9kg/m2) or severe obesity (BMI ≥40kg/m2) and diagnosed with COVID-19 (median age of 52 years), were 4 and 6 times, respectively, more likely to be hospitalised compared with patients with COVID-19 and a BMI<30kg/m2 …

Admission to intensive/critical care: … Hippisley-Cox et al analysed general practice data for over 8 million people, of which 19,486 had tested positive for COVID-19 and 1286 were admitted to ICU. The authors reported that patients living with overweight (BMI ≥25-29.9kg/m2), obesity (BMI ≥30-34.9kg/m2) or severe obesity (BMI ≥35kg/m2), compared with patients with a BMI ≥20-24.9kg/m2, had **increased odds of ICU admission of 1.64, 2.59 and 4.35** [*emphasis added*] (adjusted for age, sex, ethnicity, deprivation co-morbidity, treatment and other factors)…

Risk of mortality: Williamson et al looked at primary care data on 17 million adults, of which there were 10,926 COVID-19 deaths. **This data showed an increasing risk of death with increasing BMI** (fully adjusted for age, sex, ethnicity, deprivation and co-morbidities) with HR **1.05, 1.40 and 1.92** for people with a BMI between 30-34.9kg/m2, ≥35-39.9kg/m2 and ≥ 40kg/m2 respectively, relative to BMI <30kg/m2 [*emphasis added*].

Docherty et al41 reported that of patients hospitalised, in 208 UK hospitals, there was a 33% increased risk of mortality (after adjusting for age, sex, and major comorbidities) for those recognised by clinical staff as living with obesity."

COVID-19 Risk Calculators

[193] **QCovid algorithm**
Oxford University
https://qcovid.org/Home/AcademicLicence?licencedUrl=%2FCalculation

> "PLEASE NOTE: This implementation of the QCovid risk calculator is NOT intended for use supporting or informing clinical decision-making."

[194] **COVID-19 Mortality Risk Calculator**
Johns Hopkins & University of Maryland
https://covid19risktools.com:8443/riskcalculator

> "The tool provides an assessment of individualized risks for mortality from COVID-19 using the best publicly available information on risks associated with various predisposing factors. The tool is meant for individuals who are currently not infected and not vaccinated and it does not account for all risk-factors that might increase an individual's chance of infection and/or health complications after infection."

COVID-19 Cases, Hospitalizations, and Deaths

Official Figures and Definitions

[195] **Our World in Data**
Useful site for international comparisons of COVID-19 deaths and hospitalizations. Includes tools for the creation of custom charts.
COVID-19 Deaths: https://ourworldindata.org/covid-deaths
COVID-19 Hospitalizations: https://ourworldindata.org/covid-hospitalizations

[196] ***#Estimated COVID-19 Burden***
Centers for Disease Control and Prevention (CDC)
https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

Note: As of August 12, 2022, here are the CDC estimates for the period February 2020 to September 2021:

- 146.6 million estimated total infections
- 7.5 million estimated hospitalizations
- 921,000 estimated total deaths

"**Why CDC Estimates COVID-19 Infections, Illnesses, Hospitalizations, and Deaths**: The cumulative burden of COVID-19 is an estimate of the number of people who may have been infected, sick, hospitalized, or died as a result of a COVID-19 infection in the United States… COVID-19 infections, symptomatic illnesses, hospitalizations, and deaths might be underdetected and go unreported for a variety of reasons.

- Some people infected with SARS-CoV-2 never show symptoms (asymptomatic infection), so their infection will likely go undetected.
- Case reports sent to CDC are often missing patient information, like age or hospitalization status, or are delayed…

Because current surveillance systems do not capture all cases or deaths of COVID-19 occurring in the United States, CDC provides these estimates to better reflect the larger burden of COVID-19. CDC uses these types of estimates to inform policy decisions and public messages."

[197] **Remarks by Deborah Birx, US Coronavirus Response Coordinator**
White House press conference
April 8, 2020
https://www.youtube.com/watch?v=blZpgra3XbU

"If someone dies with COVID-19, **we are counting that as a COVID-19 death** [*emphasis added*]."

[198] **ADDED since 2/8/2008**

Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID–19)
National Center for Health Statistics — Centers for Disease Control and Prevention
April 2020
https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg03-508.pdf

> "In cases where a definite diagnosis of COVID–19 cannot be made, but it is suspected or likely (e.g., the circumstances are compelling within a reasonable degree of certainty), it is acceptable to report COVID–19 on a death certificate as 'probable' or 'presumed.' In these instances, certifiers should use their best clinical judgement in determining if a COVID–19 infection was likely…
>
> Ideally, testing for COVID–19 should be conducted, but **it is acceptable to report COVID–19 on a death certificate without this confirmation** if the circumstances are compelling within a reasonable degree of certainty."

[199] **ADDED since 2/8/2008**

COVID-19 Alert No. 2: New ICD code introduced for COVID-19 deaths
National Center for Health Statistics — Centers for Disease Contorl and Prevention
Steven Schwartz, Director of the Division for Vital Statistics
March 24, 2020
https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf
U07.1 – COVID-19
https://www.icd10data.com/icd10cm/codes/u00-u85/u00-u49/u07-/u07.1
"U07.1 is a billable ICD-10 code used to specify a medical diagnosis of covid-19. The code is valid during the fiscal year 2023 from October 01, 2022 through September 30, 2023 for the submission of HIPAA-covered transactions."

> "This email is to alert you that a newly-introduced ICD code has been implemented to accurately capture mortality data for Coronavirus Disease 2019 (COVID-19) on death certificates…
>
> **What happens if the terms reported on the death certificate indicate uncertainty?**
>
> If the death certificate reports terms such as **'probable COVID-19'** or **'likely COVID-19,'** these terms would be assigned the new ICD code. It Is not likely that NCHS will follow up on these cases…
>
> **Should "COVID-19" be reported on the death certificate only with a confirmed test?**
>
> COVID-19 should be reported on the death certificate for all decedents where the disease caused or is **assumed to have caused or contributed to death** [*emphasis in the original*]. Certifiers should include as much detail as possible based on their knowledge of the case, medical records, laboratory testing, etc. If the decedent had other chronic conditions such as COPD or asthma that may have also contributed, these conditions can be reported in Part II. (See attached Guidance for Certifying COVID-19 Deaths)."

Note: The citations below are presented in reverse, chronological order.

[200] **ADDED since 2/8/2022**
Statistical and Numerical Errors Made by the US Centers for Disease Control and Prevention During the COVID-19 Pandemic
University of California, San Francisco
Kelley Krohnert, Alyson Haslam, Tracy Beth Hoeg, and Vinay Prasad
March 7, 2023
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4381627

"**Background**: The Centers for Disease Control and Prevention (CDC) has been a major source of information during the COVID-19 pandemic, guiding policies and practices in many aspects of life. As such, it is imperative that the information be free of errors, or, if errors are made, that they are corrected quickly.

Methods: We sought to compile instances of numerical and statistical errors made by the CDC during the COVID-19 pandemic by reviewing CDC publications, press releases, interviews, meetings, and Twitter accounts. Further, we catalogued mortality data from both the National Center for Health Statistics and the CDC COVID Data Tracker and compared reported results.

Results: We documented 25 instances when the CDC reported statistical or numerical errors. Twenty (80%) of these instances **exaggerated the severity of the COVID-19 situation**...

16 (64%) pertained to children alone, and 9 (36%) pertained to both children and adults. Of the 16 cases that included data pertinent to children alone, 15 (94%) enhanced the perceived risk of COVID-19 in children, and one exaggerated their risks from the COVID-19 vaccine. Of the 3 instances where the direction of the error was 'mixed', all 3 (100%) exaggerated risks to children and understated risks to adults.

Errors included basic vital statistics such as the number of deceased children. Thirteen (52%) involved mortality statistics…

Discussion: … These errors suggest the CDC **consistently exaggerates the impact of COVID-19 on children**. At the same time, the CDC has expressed significant concern about COVID-19 misinformation. In order for the CDC to be a credible source of information, they must improve the accuracy of the data they provide."

[201] **ADDED since 2/8/2008**
CDC coding error led to overcount of 72,000 Covid deaths
The Guardian
Melody Schreiber
March 24, 2022
https://www.theguardian.com/world/2022/mar/24/cdc-coding-error-overcount-covid-deaths

"Last week, after reporting from the Guardian on mortality rates among children, the CDC corrected a "coding logic error" that had inadvertently added more than 72,000 Covid deaths of all ages to the data tracker, one of the most publicly accessible sources for Covid data.

The agency briefly noted the change in a footnote, although the note did not explain how the error occurred or how long it was in effect.

A total of 72,277 deaths in all age groups reported across 26 states were removed from the tracker 'because CDC's algorithm was accidentally counting deaths that were not Covid-19-related', Jasmine Reed, a spokesperson for the agency, told the Guardian."

[202] ***No difference in risk of hospitalisation between reported cases of the SARS-CoV-2 Delta variant and Alpha variant in Norway***
Norwegian Institute of Public Health
Lamprini Veneti, Beatriz Valcarcel Salamanca, *et al*.
September 5, 2021
https://www.medrxiv.org/content/10.1101/2021.09.02.21263014v1.full-text

"**Results**: We included 7,977 cases of Delta and 12,078 cases of Alpha. Overall, 347 (**1.7%**) cases were hospitalized [*emphasis added*]."

[203] ***Current Hospital Capacity Estimates – Snapshot***
Centers for Disease Control & Prevention
July 14, 2020
https://www.cdc.gov/nhsn/covid19/report-patient-impact.html

Note: In the Table below, the CDC estimates that **8% of all inpatient hospital-bed occupants** in the US were COVID-19 patients for the period **April 1, 2020, to July 13, 2020**.

Downloadable Dataset

The following downloadable file contains national and state estimates from the NHSN COVID-19 Module. This file will not be updated after July 14, 2020 and includes data from April 1 to July 14.

Download national and state estimates NHSN COVID-19 Module data [CSV – 600 KB]

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National Estimates

Estimates for July 13	Number (95% CI)	Percentage (95% CI)
Inpatient Beds Occupied (all Patients)	504,432 (479,075 - 529,789)	63% (62% - 64%)
Inpatient Beds Occupied (COVID-19 Patients)	64,496 (61,047 - 67,946)	8% (8% - 9%)
ICU Beds Occupied (all Patients)	75,257 (70,290 - 80,225)	61% (59% - 62%)

Updated: 07/14/2020

Statistical methods: Statistical methods were used to generate estimates of patient impact and hospital capacity measures that are representative at the national level. The estimates are based on data submitted by acute care hospitals to the NHSN COVID-19 Module. The statistical methods include weighting (to account for non-response) and multiple imputation (to account for missing data). The estimates (number and percentage) are shown along with 95% confidence intervals that reflect the statistical error that is primarily due to non-response.

Data source: Centers for Disease Control and Prevention, National Healthcare Safety Network
For more information: https://www.cdc.gov/nhsn/covid19/index.html

Inconsistent or Misleading Qualifying Practices

Note: The citations below are presented in reverse, chronological order.

[204] **ADDED since 2/8/2022**
Open Letter to the United Kingdon's Statistics Regulator (Office of National Statistics)
Norman Fenton, Martin Neil, Clare Craig, and Scott McLachlan
November 11, 2022
https://wherearethenumbers.substack.com/p/the-ons-data-on-vaccine-mortality-is

"Dear Sir/Madam,

Since the ONS [*Office of National Statistics*] began producing its covid vaccine mortality surveillance reports in 2021, we have been highlighting various anomalies in their datasets. This includes strong evidence that many of those dying shortly after vaccination were being misclassified as unvaccinated and systematic undercounting of deaths occurring within first two weeks of vaccination.

We are especially concerned about the latest ONS dataset and have produced a detailed analysis which highlights the multiple glaring anomalies in it (http://dx.doi.org/10.13140/RG.2.2.30898.07362).

We show that, in addition to further definitive evidence of the misclassification and missing deaths, there is: a) gross underestimation of the population proportion unvaccinated, and b) mortality rates that are both nonsensical in various categories and completely incompatible with historical rates.

We believe that there are multiple violations of your code of practice In particular, the dataset breaches the Quality and Value criteria numbered: Q 1.1, Q1.4 – 1.7, Q 2.4, Q 2.5, Q 3.2 – 3.5, V 1.1, V 3.2 – 3.3.

All of the anomalies in the dataset introduce bias in favour of analyses supporting vaccine 'safety and efficacy'. The fact that these data are being used as continued justification for the efficacy and safety of the covid vaccines is therefore now **a matter of national concern and scandal**. We believe that an investigation into how and why the ONS dataset is so flawed and corrupted is required. In the meantime, we call for

1. the public withdrawal of the ONS dataset and

2. the retraction of any claims made by others that are based upon it."

Response: Ed Humpherson to Norman Fenton, Martin Neil, Clare Craig and Scott McLachlan: ONS Deaths by Vaccination Status statistics
January 23, 2023
https://osr.statisticsauthority.gov.uk/correspondence/ed-humpherson-to-norman-fenton-martin-neil-clare-craig-and-scott-mclachlan-ons-deaths-by-vaccination-status-statistics/

"Thank you for contacting us with your concerns about ONS's Deaths by Vaccination Status publication and for your patience as we have carried out our investigations. It has taken us some time to respond, for which I apologise. This is because these are important issues and we wanted to consider them carefully. I have set out our thinking on the issues below….

We consider that it is therefore likely that the sample used in the Deaths by Vaccination Status publication is not representative of the general population…

Overall, then, our view is that the Deaths by Vaccination Status publication does not provide information on vaccine effectiveness or vaccine safety, and **should not be used in this way**."

[205] **ADDED since 2/8/2022**

Response to Request for Information (RFI): COVID-19 Misinformation from Official Sources During the Pandemic

Todd Rokita, Indiana Attorney General; Dr. Jay Bhattacharya, Professor at Stanford University School of Medicine; and Dr. Kulldorff former Professor at Harvard University School of Medicine
May 2, 2022
https://content.govdelivery.com/attachments/INAG/2022/05/16/file_attachments/2159907/Indiana%20Attorney%20General%20COVID%20Misinformation%20Submission.pdf

"**#1 Overcounting COVID-19**: **The official CDC numbers for COVID-19 deaths and hospitalizations are inaccurate**. The official tallies include many people who have died with rather than from COVID-19. CDC has not distinguished deaths where COVID-19 was the primary cause of death, where COVID-19 was a contributing cause of death, or where the death was entirely unrelated to COVID-19, but they incidentally tested positive.

There are three reasons for this problem. (i) The counting of COVID-19 cases and deaths is unlike the way that public health counts the incidence and mortality caused by other diseases; physicians have been advised to fill out death certificates to privilege COVID-19 as a proximal cause, even when the medical facts suggest otherwise. (ii) The population-wide testing to identify asymptomatic individuals infected with the SARS-CoV-2 virus is unprecedented in human history. (iii) Although it would have been easy, CDC has not conducted random national surveys of medical charts to determine what proportion of reported COVID-19 deaths were truly due to COVID-19. Ex-post audits of death certificates and medical records in Santa Clara County and Alameda County, California, for instance, found that in ~25% of death certificates in which COVID-19 was labeled as the primary cause of death, other causes of death were more likely. The peer-reviewed literature confirms that COVID-19 is overcounted in other developed countries. Ex post audits of death certificates should be conducted to establish an accurate death count from COVID-19."

[206] **ADDED since 2/8/2022**

Covid-19: US tracker overestimated deaths among children

British Medical Journal
Jennifer Block
March 29, 2022
https://www.bmj.com/content/376/bmj.o831

"The US's health protection agency has reduced the number of deaths it is attributing to covid-19 by more than 70 000 after what it referred to as 'coding logic errors' were highlighted on social media.

On 15 March the Centers for Disease Control and Prevention (CDC) removed 72 277 deaths, including those of 416 children, from its Covid-19 Data Tracker, which has been posting real time data collected from more than two dozen state health departments since April 2020…

The figures have been widely used by media outlets to report on deaths in the US. The UK's Guardian newspaper, for example, carried an article on 11 March with the headline, 'One-third of all US child Covid deaths occurred during Omicron surge.' This cited CDC data to say that 550 children had died from covid-19 in the US in 2022, compared with 1017 children in the preceding 22 months. The Guardian later amended the story using figures from the American Academy of Pediatrics, which put child deaths at 179 during 2022, with 735 deaths in the preceding 20 months…

Bob Anderson, chief of the mortality statistics branch at the National Center for Health Statistics who also served on covid-19 response task forces, told The BMJ that this was essentially a case of accidentally capturing deaths 'with' rather than 'from' covid."

[207] **ADDED since 2/8/2022**

Collateral Global Report 8: Understanding Definitions and Reporting of Deaths Attributed to COVID-19 in the UK – Evidence from FOI Requests

Oxford University
T. Jefferson, M. Dietrich, J. Brassey, and C. Heneghan
March 15, 2022
https://s3.eu-west-2.amazonaws.com/uploads.collateralglobal.org/2022/03/18225024/CG_Report_8_Deaths_in_the_UK.pdf

"**Background**: Death is a widely used outcome to assess the severity of pandemics. Accuracy in assigning the cause of death is of vital importance to define the impact of the agent, monitor its evolution, and compare its threat with those of other agents. Throughout the COVID-19 pandemic, there has been widespread reporting of aggregate death data with little attention paid to the accuracy of the assignment of causation…

Methods: We aimed to analyse public authorities' understanding of the assignment of cause of deaths during the SARS-CoV-2 pandemic in the UK by accessing Freedom of Information requests posed in three periods in 2020-21. By public authorities, we mean NHS Health Trusts, laboratories, and government agencies such as Public Health England and the Department of Health and Social Care…

Results: We found 800 requests from over 90 individuals. There was **no consistency** in the definition of cause of death or contributory cause of death across national bodies and in different bodies within the same nation. Nursing home providers, as well as medical practitioners, can assign a cause of death according to the Care Quality Commission. Post-mortem examinations were uncommon, the ONS did not incorporate their results in the summary of deaths by cause during the pandemic period… Some responses indicate that SARS-CoV-2 negative individuals or those whose death was **not caused** by COVID-19 were classified as 'COVID-19 deaths'. We found 14 different ways of attributing the causes of death mentioned by respondent."

[208] ***Our Most Reliable Pandemic Number Is Losing Meaning - A new study suggests that almost half of those hospitalized with COVID-19 have mild or asymptomatic cases***
The Atlantic
David Zweig
September 13, 2021
https://www.theatlantic.com/health/archive/2021/09/covid-hospitalization-numbers-can-be-misleading/620062/

> "[T]he overall tallies of COVID hospitalizations, made available on various state and federal dashboards and widely reported on by the media, do not differentiate based on severity of illness… How many patients fall into each category has been a topic of much speculation. In August, researchers from Harvard Medical School, Tufts Medical Center, and the Veterans Affairs Healthcare System decided to find out...
>
> The authors of the paper … analyzed the electronic records for nearly 50,000 COVID hospital admissions at the more than 100 VA hospitals across the country…
>
> The study found that from March 2020 through early January 2021—before vaccination was widespread, and before the Delta variant had arrived—the proportion of patients with mild or asymptomatic disease was 36 percent. From mid-January through the end of June 2021, however, that number rose to 48 percent. In other words, the study suggests that roughly **half of all the hospitalized patients showing up on COVID-data dashboards in 2021 may have been admitted for another reason entirely,** or **had only a mild presentation of disease** [*emphasis added*]."

[209] ***Fractured record keeping leaves Philly hospitals unsure which patients are vaccinated***
Philadelphia Inquirer
Jason Laughlin
August 31, 2021
https://www.inquirer.com/health/coronavirus/vaccine-records-philadelphia-covid-pennsylvania-data-20210831.html

> "A patchwork of vaccination record keeping has left hospitals with no easy way to be precise about which of their patients have received inoculations against COVID-19…
>
> 'This is what everybody's craving for,' said John Zurlo, division director of infectious disease at Thomas Jefferson University. 'You'd hope we can get really accurate information about that and right now we really don't get accurate information.'…
>
> [T]he lack of reliable vaccine records, Zurlo said, complicates efforts to precisely understand vaccine effectiveness and determine how many local hospitalizations and deaths are resulting from COVID-19 breakthrough infections."

[210] ***"For COVID" or "With COVID": Classification of SARS-CoV-2 Hospitalizations in Children***
Hospital Pediatrics
Lauren E. Kushner, Alan R. Schroeder, Joseph Kim and Roshni Mathew
August 1, 2021
https://hosppeds.aappublications.org/content/11/8/e151

> "**Discussion**: Our findings reveal that most children hospitalized with SARS-CoV-2 have asymptomatic or mild or moderate disease, and nearly one-half of these hospitalizations were not caused by infection from the virus itself."

[211] ***Adjudicating Reasons for Hospitalization Reveals That Severe Illness From COVID-19 in Children Is Rare***
Hospital Pediatrics
Amy Beck and Monica Gandhi
July 12, 2021
https://hosppeds.aappublications.org/content/early/2021/07/12/hpeds.2021-006084

> "In this issue of Hospital Pediatrics, Kushner et al conducted an extensive chart review of 117 pediatric hospitalizations with a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) polymerase chain reaction (PCR) test from May 10, 2020, to February 10, 2021 [and]…
>
> Webb et al reviewed the charts of 146 children hospitalized with a positive SARS-CoV-2 PCR test result at another large children's hospital in California from May 1, 2020, to September 30, 2020…
>
> Notably, the percentage of hospitalized children with an incidental finding of a positive SARS-CoV-2 PCR test result was remarkably similar between the two studies (45% Kushner et al; 40% Webb et al). In addition, the percentage of children deemed with severe or critical COVID-19 in the Kushner et al study was close to the percentage of children deemed significantly symptomatic in the study by Webb et al (17% vs 14%). Taken together, these studies underscore the importance of clearly distinguishing between children hospitalized with SARS-CoV-2 found on universal testing versus those hospitalized for COVID-19. **Both studies reveal that reported hospitalization rates greatly overestimate the true burden of COVID-19 in children** [*emphasis added*]."

[212] ***What to do to get your Covid vaccination added to your medical record***
CNN
Megan Marples
April 26, 2021
https://www.cnn.com/2021/04/26/health/coronavirus-vaccine-official-medical-record-wellness/index.html

> "Getting vaccinated against Covid-19 and receiving a vaccination card has become a rite of passage for many Americans who have endured the pandemic for the last year.
>
> Securing a vaccination card, however, doesn't necessarily mean your Covid-19 vaccine status is in your medical records.

Many got the vaccines at drive-in events, sports stadiums and other mass vaccination locations in their communities. If you are among the countless people who didn't get the doses at a primary care doctor's office, **there may not be any record of the vaccination on file with your doctor** [*emphasis added*]."

[213] **Video (:45s): Remarks by Ngozi O. Ezike, Director**
Illinois Department of Public Health press conference
May 25, 2020
https://odysee.com/@LockdownSkepticism:f/Department-of-Public-Health-Director:d

Ezike: "I just want to be clear in terms of the definition of 'people dying of COVID.' The case definition is very simplistic. It means, at the time of death, it was a COVID positive diagnosis. That means that if you were in hospice and had already been given a few weeks to live, and then you were also found to have COVID, that would be counted as a COVID death. It means, technically even if you died of a clear alternate cause, but you had COVID at the same time, **it's still listed as a COVID death** [*emphasis added*]. Everyone who is listed as a COVID death, doesn't mean that was the cause of the death, but they had COVID at the time of death. I hope that's helpful."

[214] ***Why have so many coronavirus patients died in Italy?***
The Telegraph
Sarah Newey
March 23, 2020
https://www.telegraph.co.uk/global-health/science-and-disease/have-many-coronavirus-patients-died-italy/

"According to Prof Walter Ricciardi, scientific adviser to Italy's minister of health, the country's mortality rate is far higher due to demographics – the nation has the second oldest population worldwide – and the manner in which hospitals record deaths…

But Prof Ricciardi added that Italy's death rate may also appear high because of how doctors record fatalities.

'The way in which we code deaths in our country is very generous in the sense that **all the people who die in hospitals with the coronavirus are deemed to be dying of the coronavirus**.

'On re-evaluation by the National Institute of Health, **only 12 per cent of death certificates have shown a direct causality from coronavirus**, while 88 per cent of patients who have died have at least one pre-morbidity – many had two or three [*emphasis added*],' he says."

Influence of Financial Incentives

Note: The citations below are presented in reverse, chronological order.

[215] **ADDED since 2/8/2008**
New COVID-19 Treatments Add-On Payment (NCTAP)
Centers for Medicare & Medicaid Services
Last modified December 13, 2022
https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap

CMS issued an Interim Final Rule with Comment Period that established the New COVID-19 Treatments Add-on Payment (NCTAP) under the Medicare Inpatient Prospective Payment System (IPPS). The NCTAP, designed to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments, is effective from November 2, 2020, until the end of the fiscal year in which the COVID-19 public health emergency (PHE) ends.

Through the NCTAP, **the Medicare Program will provide an enhanced payment** for eligible inpatient cases that use certain new products with current FDA approval or emergency use authorization (EUA) to treat COVID-19, including the following:

- On August 23, 2020, the FDA issued (reissued on November 30, 2020, and revised on March 9, 2021) an EUA for the use of **COVID-19 convalescent plasma** for treating COVID-19 in hospitalized patients
- On October 22, 2020, the FDA approved **remdesivir** (Veklury) for the treatment of COVID-19 for adults and certain pediatric patients requiring hospitalization
- On November 19, 2020, the FDA issued (and amended on December 20, 2021) an EUA for the use of **baricitinib** (Olumiant) for the treatment of suspected or laboratory confirmed COVID-19 in certain hospitalized patients
- On December 22, 2021, the FDA issued an EUA for **molnupiravir** for the treatment of mild-to-moderate COVID-19 in certain adults who are at high-risk for progression to severe COVID-19, including hospitalization or death.
- On December 23, 2021, the FDA issued an EUA for **PAXLOVID** (nirmatrelvir co-packaged with ritonavir) for the treatment of mild-to-moderate COVID-19...
- On November 8, 2022, the FDA issued an EUA for **Kineret** (anakinra) injection for the treatment of COVID-19...

For eligible cases, the NCTAP is equal to the lesser of these:

- 65% of the operating outlier threshold for the claim
- 65% of the amount by which the costs of the case exceed the standard Diagnosis-Related Group (DRG) payment (including the adjustment to the relative weight under Section 3710 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

[216] ***Bounty on Your Life: Hospitals' Incentive Payments for COVID-19***
Association of American Physicians and Surgeons
Elizabeth Lee Vliet and Ali Shultz
November 17, 2021
https://aapsonline.org/bidens-bounty-on-your-life-hospitals-incentive-payments-for-covid-19/

"The combination that enables this tragic and avoidable loss of hundreds of thousands of lives includes (1) The CARES Act, which provides hospitals with bonus incentive payments for all things related to COVID-19 (testing, diagnosing, admitting to hospital, use of remdesivir and ventilators, reporting COVID-19 deaths, and vaccinations) and (2) waivers of customary and long-standing patient rights by the Centers for Medicare and Medicaid Services (CMS)…

The CARES Act provides **incentives for hospitals to use treatments dictated solely by the federal government** under the auspices of the NIH. These 'bounties' must be paid back if not 'earned' by making the COVID-19 diagnosis and following the COVID-19 protocol [*emphasis added*].

The hospital payments include:

- A "free" required PCR test in the Emergency Room or upon admission for every patient, with government-paid fee to hospital.
- Added bonus payment for each positive COVID-19 diagnosis.
- Another bonus for a COVID-19 admission to the hospital.
- A 20 percent "boost" bonus payment from Medicare on the entire hospital bill for use of remdesivir instead of medicines such as Ivermectin.
- Another and larger bonus payment to the hospital if a COVID-19 patient is mechanically ventilated.
- More money to the hospital if cause of death is listed as COVID-19, even if patient did not die directly of COVID-19.
- A COVID-19 diagnosis also provides extra payments to coroners."

[217] **ADDED since 2/8/2022**
Covid vaccine profits mint 9 new pharma billionaires
CNN Business
Hanna Ziady
May 21, 2021
https://www.cnn.com/2021/05/21/business/covid-vaccine-billionaires/index.html

"Covid-19 vaccines have created at least nine new billionaires after shares in companies producing the shots soared…

Moderna's share price has gained more than 700% since February 2020, while BioNTech has surged 600%. CanSino Biologics' stock is up about 440% over the same period…

Vaccine billions

BioNTech, which received €325 million ($397 million) from the German government for the development of the vaccine, said it is committed to supplying low-income countries with its vaccine at cost…

BioNTech made a net profit of €1.1 billion ($1.3 billion) in the first three months of the year, largely thanks to its share of sales from the Covid-19 vaccine…

Moderna's Covid-19 vaccine sales hit $1.7 billion in the first three months of this year and it had its first profitable quarter ever, the company reported earlier this month. Goldman Sachs (GS) expects Moderna to make $13.2 billion in Covid-19 vaccine revenue in 2021. The company has received billions of dollars in funding from the US government for development of its vaccine."

[218] **ADDED since 2/8/2021**

Biden-Harris Administration Increases Medicare Payment for Life-Saving COVID-19 Vaccine

Centers for Medicare & Medicaid Services
March 15, 2021
https://www.cms.gov/newsroom/press-releases/biden-harris-administration-increases-medicare-payment-life-saving-covid-19-vaccine

"Effective for COVID-19 vaccines administered on or after March 15, 2021, the national average payment rate for physicians, hospitals, pharmacies and many other immunizers will be $40 to administer each dose of a COVID-19 vaccine. This represents an increase from approximately $28 to $40 for the administration of single-dose vaccines, and an increase from approximately $45 to $80 for the administration of COVID-19 vaccines requiring two doses."

[219] **ADDED since 2/8/2008**

Federal Register, Vol. 85, No. 216

Department of the Treasury — Internal Revenue Service
November 6, 2020
https://www.govinfo.gov/content/pkg/FR-2020-11-06/pdf/2020-24332.pdf

"**Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency…**

SUMMARY: This interim final rule with request for comments (IFC) discusses CMS's [*Centers for Medicare & Medicaid Services*] implementation of section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which established **Medicare Part B coverage** and **payment** for Coronavirus Disease 2019 (COVID–19) vaccine and its administration. This IFC implements requirements in the CARES Act that providers of COVID–19 diagnostic tests make public their cash prices for those tests and establishes an enforcement scheme to enforce those requirements. This rule also establishes an **add-on payment** for cases involving the use of new COVID–19 treatments under the Medicare Inpatient Prospective Payment System (IPPS). This IFC provides for separate payment for new COVID–19 treatments under the Outpatient Prospective Payment System (OPPS) for the remainder of the PHE [*public health emergency*] for COVID–19 when these treatments are provided at the same time as a Comprehensive Ambulatory Payment Classification (C– APC)

service.

[220] **ADDED since 2/8/2022**

Hearing Transcript: *The Urgent Need for a National Plan to Contain the Coronavirus*
Select Subcommittee on the Coronavirus Crisis of the Committee on Oversight and Reform — House of Representatives
Testimony of Dr. Robert Redfield, former Director of the Centers for Disease Control and Prevention
July 31, 2020
https://docs.house.gov/meetings/VC/VC00/20200731/110912/HHRG-116-VC00-Transcript-20200731.pdf

Mr. Blaine Luetkemeyer (rep. MO): "One of the things that concerns me also is… with regards to the sort of perverse incentive for the medical folks to claim that somebody died of COVID versus, if it was an automobile accident, for instance, as long as you have COVID in your system, you get to claim it as a COVID death, **which means you get more money** as the attending physician, hospital, whatever.

And he acknowledged that the statistics he's getting from the states are overinflated. We found that the Governor of Colorado, who is a Democrat, actually did research on this and found he had to get rid of 12 percent of the deaths that were recorded in the state.

Dr. Redfield, would you like to comment on that a little bit, about the perverse incentive? And is there an effort to try and do something different in the way that these deaths are recorded so we actually have better records and better numbers, better data to go with?"

Dr. Redfield: "**I think you're correct**, in that we've seen this in other disease processes, too, really. In the HIV epidemic, somebody may have heart attack but also have HIV. The hospital would prefer the DRG for HIV because there's greater reimbursement. So, **I do think there's some reality to that**."

[221] **ADDED since 2/8/2022**

Furor Erupts: Billions Going To Hospitals Based On Medicare Billings, Not COVID-19
Kaiser Health News
Jay Hancock, Phil Galewitz, and Elizabeth Lucas
April 10, 2020
https://khn.org/news/furor-erupts-billions-going-to-hospitals-based-on-medicare-billings-not-covid-19/

"States such as Minnesota, Nebraska and Montana, which the pandemic has touched relatively lightly, are getting more than **$300,000 per reported COVID-19 case** in the $30 billion, according to a Kaiser Health News analysis.

On the other hand, New York, the worst-hit state, would receive only $12,000 per case. Florida is getting $132,000 per case. KHN relied on a state breakdown provided to the House Ways and Means Committee by HHS along with COVID-19 cases tabulated by The New York Times."

[222] **Interview with Dr. Scott Jensen**
Fox News
April 8, 2020
https://odysee.com/@barrythetruth:2/Dr--Scott-Jensen-With-Laura-Ingraham---The-Ridiculous-CDC-Guidlines:4

> "Right now Medicare is determining that if you have a COVID-19 admission to the hospital, you'll get paid $13,000. If that COVID-19 patient goes on a ventilator, you get $39,000, three times as much. Nobody can tell me after 35 years in the world of medicine that sometimes those kinds of things impact on what we do."

[223] **ADDED since 2/8/2008**
The Biopharmaceutical Industry Provides 75% Of The FDA's Drug Review Budget. Is This A Problem?
Forbes
John LaMattina
June 28, 2018
https://www.forbes.com/sites/johnlamattina/2018/06/28/the-biopharmaceutical-industry-provides-75-of-the-fdas-drug-review-budget-is-this-a-problem/?sh=7141b9e649ec

> "Caroline Chen of ProPublica has written a provocative article challenging the objectivity of the FDA in its approval of new drugs. Entitled: 'FDA Repays Industry by Rushing Risky Drugs to Market', Chen contends that the agency is beholden to the biopharmaceutical industry which pays three quarters of the FDA's budget used for the drug review process. This is an astounding number. Is any other federal agency supported to this extent by the industry it regulates? Given this level of support, one might assume that the FDA would bend over backwards to meet the needs of its financial backers…"

[224] **ADDED since 2/8/2008**
FDA Repays Industry by Rushing Risky Drugs to Market
ProPublica
Caroline Chen
June 26, 2018
https://www.propublica.org/article/fda-repays-industry-by-rushing-risky-drugs-to-market

> "The FDA is increasingly green-lighting expensive drugs despite dangerous or little-known side effects and inconclusive evidence that they curb or cure disease. Once widely assailed for moving slowly, today the FDA reviews and approves drugs faster than any other regulatory agency in the world. Between 2011 and 2015, the FDA reviewed new drug applications more than 60 days faster on average than did the European Medicines Agency…
>
> 'Instead of a regulator and a regulated industry, we now have a partnership,' said Dr. Michael Carome, director of the health research group for the nonprofit advocacy organization Public Citizen, and a former U.S. Department of Health and Human Services official. 'That relationship has tilted the agency away from a public health perspective to an industry friendly perspective.'
>
> While the FDA over the past three decades has implemented at least four major routes to faster approvals — the current commissioner, Dr. Scott Gottlieb, is easing even more drugs' path to market. The FDA okayed 46 'novel' drugs — whose chemical structure hadn't been

previously approved — in 2017, the most in at least 15 years. At the same time, it's rejecting fewer medications. In 2017, the FDA's Center for Drug Evaluation and Research denied 19.7 percent of all applications for new drugs, biologics, and efficacy supplements, down from a 2010 peak of 59.2 percent, according to agency data…

The FDA's growing emphasis on speed has come at the urging of both patient advocacy groups and industry, which began in 1992 to contribute to the salaries of the agency's drug reviewers in exchange for time limits on reviews. In 2017, **pharma paid 75 percent** — or $905 million — **of the agency's scientific review budgets for branded and generic drugs**, compared to 27 percent in 1993."

Issues with Polymerase Chain Reaction (PCR) Testing

[225] ***White Paper: Covid Recovery – A Scientific Approach***
COVID-19 Ireland
December 2020
https://covidrecovery.ie/
Medical Signatories:
https://drive.google.com/file/d/1Mfc85i17Z9d2CyLzlf0bOqin3vbXbQfd/view

"**Is PCR an appropriate tool to inform policy?** We are concerned about the implementation of PCR as the standard test for SARS-CoV-2. PCR has standard false-positive rates of 1 - 3%33 and up to 4% in the UK. Suggesting that every positive PCR result constitutes an infectious "case", is not accurate… This clearly misrepresents the real-world situation, and has undue influence on important policy interventions. In addition, PCR cannot distinguish **infectious live virus from residual dead virus** or viral fragments from previous infection [*emphasis added*]. Therefore many 'cases' have no real meaning in terms of medical status or transmission potential – further misleading clinicians and policymakers alike.

The PCR test functions by amplification of tiny fragments of virus – 'magnifying" them in a series of cycles. The number of cycles required to identify viral genetic material – the cycle threshold (Ct), correlates inversely with the amount of viral genetic material actually present in the original specimen. If there is little virus present, (probably not enough to be infectious) and the test has a high cycle threshold (cycle thresholds are set by the individual test kit manufacturers), it will probably identify harmless viral fragments and the test will be deemed 'positive'. In Ireland, Ct value cut-offs of 35-45 are the norm. **High Ct values (over 35 or even 30) suggest a non- infectious patient** [*emphasis added*], often due to low viral load (or the test identifying dead viral genetic material from a previous infection, or often from contamination in the test process). In contrast, low Ct values are more likely to indicate a high viral load, and therefore an infectious patient…"

"**Problems and inconsistencies with PCR testing have been documented extensively**: non standardised specimen collection techniques; no gold standard test yet identified; different tests used in different labs; no standardised acceptable Ct values; inconsistent quality assurance programs; false positives; identification of irrelevant dead viral genetic material which can persist for months after infection; potential contamination of specimens, to name a few. Poorly designed PCR testing regimes can drive cases in infectious disease outbreaks and several reports exist of 'pseudo' epidemics caused by over sensitive or poorly regulated PCR testing regimes. Patients with Ct values of >35 are extremely unlikely to be infectious unless they have been tested in the early stages of infection."

[226] ***COVID-19 Real-Time PCR Kit Instructions For Use***
World Health Organization
https://www.who.int/diagnostics_laboratory/eual/eul_0535_196_00_covid19_real_time_pcr_kit_ifu.pdf

"**9.2 Interpretation of Results**… The Ct [cycle threshold] value of any fluorescent detection channel for a positive control should be no higher than 34"

[227] **Video (4m): Commentary by Kary Mullis, inventor of the polymerase chain reaction (PCR) technique and Nobel Prize winner**
Date unknown
https://www.bitchute.com/video/DNylqfqjBEpl/
https://www.bitchute.com/video/wOSeTz57xrCF/

> **Audience question**: "How do they misuse PCR to estimate all these supposed free, viral RNAs that may or may not be there?"
>
> **Mullis**: "… I don't think you can misuse PCR… With PCR, if you do it well, you can find almost anything in anybody. It starts making you believe in the sort of Buddhist notion that everything is contained in everything else. Because if you can amplify one single molecule up to something that you can really measure, which PCR can do, there are just very few molecules that you don't have at least one single one of in your body…
>
> It [*PCR*] tells you something about nature and what's there. It allows you to take a very miniscule amount of anything and make it measurable…
>
> PCR is just a process that's used to make a whole lot of something out of something. **It doesn't tell you that you're sick**, and it doesn't tell you that the thing you ended up with was going to hurt you, or anything like that [*emphasis added*]."

[228] ***Faith in Quick Test Leads to Epidemic That Wasn't***
New York Times
Gina Kolata
January 22, 2007
https://web.archive.org/web/20191019005156/https://www.nytimes.com/2007/01/22/health/22whoop.html

> "It was the start of a bizarre episode at the medical center: the story of **the epidemic that wasn't** [*emphasis added*]…
>
> Not a single case of whooping cough was confirmed with the definitive test, growing the bacterium, Bordetella pertussis, in the laboratory. Instead, it appears the health care workers probably were afflicted with ordinary respiratory diseases like the common cold.
>
> Now, as they look back on the episode, epidemiologists and infectious disease specialists say the problem was that they placed too much faith in a quick and highly sensitive molecular test that led them astray…
>
> At Dartmouth the decision was to use a test, P.C.R., for polymerase chain reaction. It is a molecular test that, until recently, was confined to molecular biology laboratories."

Note: The citations below are presented in reverse, chronological order.

[229] ***Press Briefing by White House COVID-19 Response Team and Public Health Officials***
The White House
Comments by Rochelle Walensky, Director of the Centers for Disease Control and Prevention
December 29, 2021
https://www.whitehouse.gov/briefing-room/press-briefings/2021/12/29/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-76/

> **Walensky**: "We do know the vast majority of viral transmission happens in those first five days, somewhere in the 85 to 90 percent range. So if a person can isolate for the first five days, they absolutely should.
>
> Many are asking why do we not require a test at the end of the five days of isolation for those who are infected. We know that PCR testing would not be helpful in this setting, as people can remain PCR positive for **up to 12 weeks after infection** and **long after they are transmissible** and **infectious** [*emphasis added*]."

[230] **ADDED since 2/8/2020**
Analysis of the initial lot of the CDC 2019-Novel Coronavirus (2019-nCoV) real-time RT-PCR diagnostic panel
PLOS One — Centers for Disease Control and Prevention
Justin S. Lee, Jason M. Goldstein, *et al.*
December 15, 2021
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0260487

> "**Abstract**: At the start of the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) designed, manufactured, and distributed the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel for SARS-CoV-2 detection. The diagnostic panel targeted three viral nucleocapsid gene loci (N1, N2, and N3 primers and probes) to maximize sensitivity and to provide redundancy for virus detection if mutations occurred. After the first distribution of the diagnostic panel, state public health laboratories reported fluorescent signal in the absence of viral template (false-positive reactivity) for the N3 component and to a lesser extent for N1. This report describes the findings of an internal investigation conducted by the CDC to identify the cause(s) of the N1 and N3 false-positive reactivity…
>
> **Discussion**: The N1 and N3 components of the first distribution (Lot #20–0121) of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel suffered from sporadic **false-positive reactivity**."

[231] ***CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel***
Centers for Disease Control & Prevention
Effective July 21, 2021
https://www.fda.gov/media/134922/download

> "Interpretation of Results and Reporting… 2019-nCoV Markers (N1 and N2)… When all controls exhibit the expected performance, a specimen is considered positive for 2019-nCoV if all 2019-nCoV marker (N1, N2) cycle threshold growth curves **cross the threshold line within 40.00 cycles** (< 40.00 Ct) [*emphasis added*]. The RNase P may or may not be positive as described above, but the 2019-nCoV result is still valid."

[232] **Plaintiffs Motion for Preliminary Injunction: *America's Frontline Doctors, et al., vs. Xavier Becerra, Secretary of the US Department of Health and Human Services***
Lowell H. Becraft, Jr., Thomas Renz, *et al*. (Attorney's for Plaintiffs)
July 19 2021
https://img1.wsimg.com/blobby/go/3c6a0774-cfad-46fa-aa97-af5aa5e74f00/M%20for%20PI%20file%20stamped.pdf

> **A. The Unlawful Vaccine Emergency Use Authorizations**…
>
> Virtually all scientists, including Dr. Fauci, agree that any PCR test run at a CT value of 35-cycles or greater is useless… A study funded by the French government showed that even at 35-cycles, the false positivity rate is as high as 97%. Despite this, a majority of the PCR tests for COVID-19 deployed under EUAs in the United States are run at 35-45 cycles in accordance with manufacturer instructions. Under the EUAs issued by the FDA, there is no flexibility to depart from the manufacturer's instructions and change the way in which the test is administered or interpreted. The chart below shows that all major PCR tests in use in the United States are run at cycles of up to 35 or higher."

Manufacturer	Manufacturer's Recommended Cycle Threshold
Xiamen Zeesan SARS-CoV-2 Test Kit (Real-time PCR)	45 cycles
Opti Sars CoV-2 RT-PCR Test	45 cycles
Quest SARS-CoV-2rRT-PCR Test	40 cycles
CDC 2019-Novel Coronavirus Real Time (RT-PCR Diagnostic Panel) Test	40 cycles
Wren Labs COVID-19 PCR Test	38 cycles
LabCorp COVID-19 RT-PCR Test	35 cycles

[233] **Letter: *Duration of Culturable SARS-CoV-2 in Hospitalized Patients with Covid-19***
New England Journal of Medicine
Min-Chul Kim, Chunguang Cui, *et al*.
February 18, 2021
https://www.nejm.org/doi/full/10.1056/NEJMc2027040

> "The data reported here represent all the patients with Covid-19, as confirmed by positive real-time reverse transcriptase–polymerase chain reaction (RT-PCR) testing, who were hospitalized at Chung-Ang University Hospital in Seoul, South Korea, between February and June 2020."

"Viral culture was positive only in samples with a cycle-threshold value of **28.4 or less** [*emphasis added*]. The incidence of culture positivity decreased with an increasing time from symptom onset and with an increasing cycle-threshold value."

[234] ***Op-Ed: Why PCR Cycle Threshold Is Useful in Coronavirus Testing***
Medpage Today
Robert Hagen
January 4, 2021
https://www.medpagetoday.com/infectiousdisease/covid19/90508

"So how does a qualitative RT-PCR test work? Basically, the manufacturer sets the test to turn off the cycling or amplification process when a certain number is hit. For a qualitative test set at 40, after 40 amplification cycles, if any viral material is detected, it turns off and is reported as positive. If none is detected, it would be reported as negative. If the number of amplification cycles was really 15 or 25, it would still run until it gets to 40 and be reported as positive.

With these type of tests, it's critical to use an agreed-upon cycle threshold value such as 33 (CDC) or 35 (Dr. Fauci) rather than setting it at a potentially misleading 40 or 45. **Many of the current tests in use are preset by the manufacturer to these higher numbers** [*emphasis added*].

The World Health Organization issued a notice last week telling the labs 'the cut-off should be manually adjusted to ensure that specimens with high Ct values are not incorrectly assigned SARS-CoV-2 detected due to background noise.' Could this be a reason why many people test positive but remain asymptomatic? In that same memo, WHO said all labs should report the cycle threshold value to treating physicians…"

"Above that level [*Ct value of 35*], Fauci has said the test is just finding destroyed nucleotides, not virus capable of replicating."

[235] ***Viral cultures for COVID-19 infectious potential assessment – a systematic review***
Clinical Infectious Diseases
T. Jefferson, E.A. Spencer, J. Brassey, and C. Heneghan
December 3, 2020
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217

"**Results**: We included 29 studies reporting attempts at culturing, or observing tissue infection by, SARS-CoV-2 in sputum, nasopharyngeal or oropharyngeal, urine, stool, blood and environmental specimens… The data suggest a relationship between the time from onset of symptom to the timing of the specimen test, cycle threshold (Ct) and symptom severity. Twelve studies reported that Ct values were significantly lower and log copies higher in specimens producing live virus culture. Two studies reported the odds of live virus culture reduced by approximately 33% for every one unit increase in Ct."

"**Conclusion**: Complete live viruses are necessary for transmission, not the fragments identified by PCR. Prospective routine testing of reference and culture specimens and their relationship to symptoms, signs and patient co-factors should be used to define the reliability of PCR for assessing infectious potential. Those with high cycle threshold are unlikely to have infectious potential."

[236] ***External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results***.
Corman-Drosten Review Report
Pieter Borger, Bobby Rajesh Malhotra, *et al*.
November 27, 2020
https://cormandrostenreview.com/report/

> "**Abstract**: In the publication entitled "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR" (Eurosurveillance 25(8) 2020) the authors present a diagnostic workflow and RT-qPCR protocol for detection and diagnostics of 2019-nCoV (now known as SARS-CoV-2), which they claim to be validated, as well as being a robust diagnostic methodology for use in public-health laboratory settings.
>
> In light of all the consequences resulting from this very publication for societies worldwide, a group of independent researchers performed a point-by-point review of the aforesaid publication in which 1) all components of the presented test design were cross checked, 2) the RT-qPCR protocol-recommendations were assessed w.r.t. good laboratory practice, and 3) parameters examined against relevant scientific literature covering the field.
>
> The published RT-qPCR protocol for detection and diagnostics of 2019-nCoV and the manuscript suffer from numerous technical and scientific errors, including insufficient primer design, a problematic and insufficient RT-qPCR protocol, and the absence of an accurate test validation. Neither the presented test nor the manuscript itself fulfils the requirements for an acceptable scientific publication. Further, serious conflicts of interest of the authors are not mentioned. Finally, the very short timescale between submission and acceptance of the publication (24 hours) signifies that a systematic peer review process was either not performed here, or of problematic poor quality. We provide compelling evidence of several scientific inadequacies, errors and flaws.
>
> Considering the scientific and methodological blemishes presented here, we are confident that the editorial board of Eurosurveillance has no other choice but to retract the publication.
>
> What is important when designing an RT-PCR Test and the quantitative RT-qPCR test described in the Corman-Drosten publication? …
>
> **Concise Review Report**: There are **ten fatal problems with the Corman-Drosten paper** which we will outline and explain in greater detail in the following sections [*emphasis added*]…
>
> 3. The number of amplification cycles (less than 35; preferably 25-30 cycles);
>
> In case of virus detection, >35 cycles only detects signals which do not correlate with infectious virus as determined by isolation in cell culture [reviewed in 2]; if someone is tested by PCR as positive when a threshold of 35 cycles or higher is used (**as is the case in most laboratories in Europe & the US**), the probability that said person is actually infected is less than 3% [*emphasis added*], the probability that said result is a false positive is 97%…
>
> The maximum reasonably reliable Ct value is 30 cycles. Above a Ct of 35 cycles, rapidly increasing numbers of false positives must be expected. PCR data evaluated as positive after a Ct value of 35 cycles are completely unreliable… Further, scientific studies show that only non-infectious (dead) viruses are detected with Ct values of 35."

[237] ***Cell-based Culture Informs Infectivity and Safe De-Isolation Assessments in Patients with Coronavirus Disease 2019***
Clinical Infectious Diseases
Kerri Basile, Kenneth McPhie, *et al*.
October 24, 2020
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1579/5937368

"**Background**: The detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA by reverse-transcription polymerase chain reaction (PCR) does not necessarily indicate shedding of infective virions. There are limited data on the correlation between the isolation of SARS-CoV-2, which likely indicates infectivity, and PCR."

"**Methods**: … No clinical samples with PCR Ct values >32 resulted in positive viral cultures."

"**Results**: The highest Ct for the N gene target in any clinical sample where SARS-COV-2 was successfully cultured was 32. Based on this result and the Ct cutoff value of 37 determined by PCR of TCID dilutions and incorporating a 1-log margin of error, we were confident that any clinical sample with a Ct of ≥37 was not indicative of viable virus."

[238] ***One number could help reveal how infectious a COVID-19 patient is. Should test results include it?***
Science magazine
Robert F. Service
September 29, 2020
https://www.science.org/news/2020/09/one-number-could-help-reveal-how-infectious-covid-19-patient-should-test-results

"Standard tests identify SARS-CoV-2 infections by isolating and amplifying viral RNA using a procedure known as the polymerase chain reaction (PCR), which relies on multiple cycles of amplification to produce a detectable amount of RNA. The CT value is the number of cycles necessary to spot the virus; PCR machines stop running at that point. If a positive signal isn't seen after **37 to 40 cycles**, the test is negative [*emphasis added*]. But samples that turn out positive can start out with vastly different amounts of virus, for which the CT value provides an inverse measure. A test that registers a positive result after 12 rounds, for a CT value of 12, starts out with more than 10 million times as much viral genetic material as a sample with a CT value of 35."

"In a study published this week in Clinical Infectious Diseases, researchers led by Bernard La Scola, an infectious diseases expert at IHU-Méditerranée Infection, examined 3790 positive samples with known CT values to see whether they harbored viable virus, indicating the patients were likely infectious. La Scola and his colleagues found that 70% of samples with CT values of 25 or below could be cultured, compared with less than 3% of the cases with CT values above 35."

[239] **Correspondence:** ***Correlation Between 3790 Quantitative Polymerase Chain Reaction–Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates***
Clinical Infectious Diseases
Rita Jaafar, Sara Aherfi, *et al*.
September 28, 2020
https://academic.oup.com/cid/article/72/11/e921/5912603

> "The outbreak of the coronavirus disease 2019 (COVID-19) pandemic due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was declared a pandemic on 12 March 2020 by the World Health Organization. A major issue related to the outbreak has been to correlate viral RNA load obtained after reverse-transcription polymerase chain reaction (RT-PCR) and expressed as the cycle threshold (Ct) with contagiousness and therefore duration of eviction from contacts and discharge from specialized infectious disease wards. Several recent publications, based on more than 100 studies, have attempted to propose a cutoff Ct value and duration of eviction, with a consensus at approximately Ct >30 and at least 10 days, respectively. However, in an article published in Clinical Infectious Diseases, Bullard et al reported that patients could not be contagious with Ct >25 as the virus is not detected in culture above this value."
>
> "Since the beginning of the epidemic, we have performed in our institute 250,566 SARS-CoV-2 RT-PCR for 179,151 patients, of which 13,161 (7.3%) tested positive... It can be observed that **at Ct=25, up to 70% of patients remain positive in culture and that at Ct=30 this value drops to 20%**. At Ct=35, the value we used to report a positive result for PCR, < 3% of cultures are positive [*emphasis added*]."

[240] ***Your Coronavirus Test Is Positive. Maybe It Shouldn't Be***.
New York Times
Apoorva Mandavilli
Updated September 17, 2020
https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html

> "**Most [PCR] tests set the limit at 40 [cycles]. A few at 37**. This means that you are positive for the coronavirus if the test process required up to 40 cycles, or 37, to detect the virus [*emphasis added*].
>
> Tests with thresholds so high may detect not just live virus but also genetic fragments, leftovers from infection that pose no particular risk — akin to finding a hair in a room long after a person has left, Dr. Mina said.
>
> Any test with a cycle threshold above 35 is too sensitive, agreed Juliet Morrison, a virologist at the University of California, Riverside. 'I'm shocked that people would think that 40 could represent a positive,' she said.
>
> A more reasonable cutoff would be 30 to 35, she added. Dr. Mina said he would set the figure at 30, or even less. Those changes would mean the amount of genetic material in a patient's sample would have to be 100-fold to 1,000-fold that of the current standard for the test to return a positive result — at least, one worth acting on."

[241] **Video: *Interview with Dr. Anthony Fauci***
This Week in Virology
July 16, 2020
https://www.youtube.com/watch?v=a_Vy6fgaBPE&t=241s

> **Fauci (starting at 4:01)**: "What is now sort of evolving into a bit of a standard is that if you get a cycle threshold of 35 or more, that the chances of it being replication competent [*i.e., accurate*] are **miniscule**… It's very frustrating for the patients, as well as the physicians. Somebody comes in and they repeat their PCR and it's like 37 cycle threshold, but you almost can never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, ya gotta say, you know, it's just **dead nucleotides**, period [*emphasis added*]."

[242] ***Guidance and Standard Operating Procedure COVID-19 Virus Testing in NHS Laboratories***
National Health Service (England)
June 2020
https://www.rcpath.org/uploads/assets/90111431-8aca-4614-b06633d07e2a3dd9/Guidance-and-SOP-COVID-19-Testing-NHS-Laboratories.pdf

> "**5.0 Testing Standard Operating Procedure**… Where Ct values are below an agreed value (based on analysis of Proficiency Testing performance and other local testing data) with satisfactory quality control parameters including internal control performance, the result is considered valid and should be telephoned and a report issued as a final result. Any such positive result will be recorded as 'confirmed' for Public Health reporting purposes and will be notifiable under recent legislation.
>
> Results where:
>
> - the **Ct value is => 40** [*emphasis added*], AND/OR
> - there is an abnormal assay curve, AND/OR
> - the clinical context makes the positive result highly unexpected
>
> should be considered interim or held until reviewed by a laboratory clinician."

[243] ***Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples***
Clinical Infectious Diseases
Jared Bullard, Kerry Dust, *et al*.
May 22, 2020
https://academic.oup.com/cid/article/71/10/2663/5842165

> "**Background**: Reverse-transcription polymerase chain reaction (RT-PCR) has become the primary method to diagnose viral diseases, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). RT-PCR detects RNA, not infectious virus; thus, its ability to determine duration of infectivity of patients is limited. Infectivity is a critical determinant in informing public health guidelines/interventions. Our goal was to determine the relationship between E gene SARS-CoV-2 RT-PCR cycle threshold (Ct) values from respiratory samples, symptom onset to test (STT), and infectivity in cell culture."

"**Conclusions**: SARS-CoV-2 Vero cell infectivity was only observed for RT-PCR Ct < 24 and STT < 8 days. Infectivity of patients with Ct > 24 and duration of symptoms > 8 days may be low. This information can inform public health policy and guide clinical, infection control, and occupational health decisions. Further studies of larger size are needed."

[244] ***Viral RNA load as determined by cell culture as a management tool for discharge of SARS-CoV-2 patients from infectious disease wards***
European Journal of Clinical Microbiology & Infectious Diseases
Bernard la Scola, Marion Le Bideau, *et al*.
April 27, 2020
https://link.springer.com/article/10.1007%2Fs10096-020-03913-9

"**Abstract**: In a preliminary clinical study, we observed that the combination of hydroxychloroquine and azithromycin was effective against SARS-CoV-2 by shortening the duration of viral load in Covid-19 patients. It is of paramount importance to define when a treated patient can be considered as no longer contagious. Correlation between successful isolation of virus in cell culture and Ct value of quantitative RT-PCR targeting E gene suggests that patients with Ct above 33–34 using our RT-PCR system are not contagious and thus can be discharged from hospital care or strict confinement for non-hospitalized patients."

"**Introduction**: … We observed a significant relationship between Ct value and culture positivity rate (Fig. 1). Samples with Ct values of 13–17 all led to positive culture. **Culture positivity rate then decreased progressively according to Ct values to reach 12% at 33 Ct**. No culture was obtained from samples with Ct > 34 [*emphasis added*]."

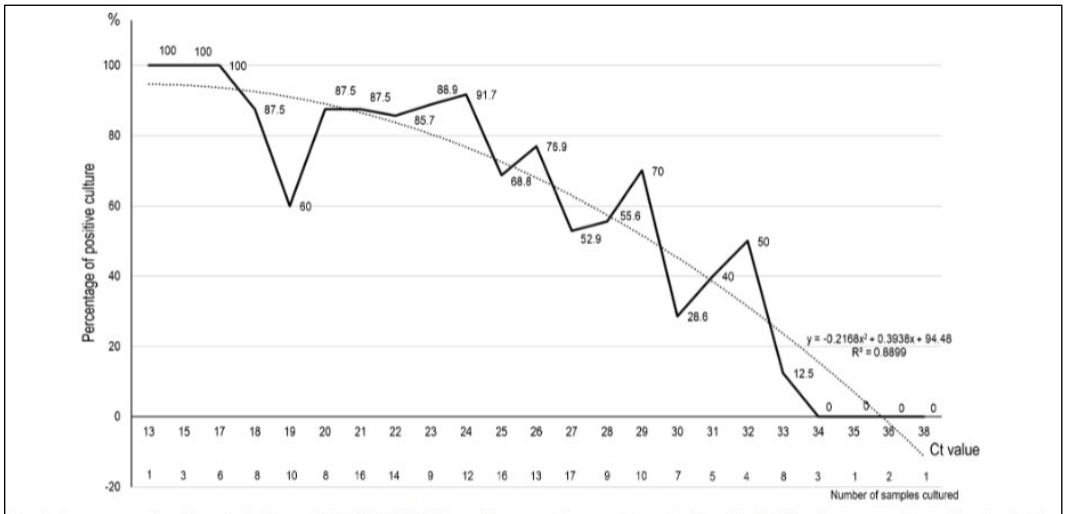


Fig. 1 Percentage of positive viral culture of SARS-CoV-2 PCR-positive nasopharyngeal samples from Covid-19 patients, according to Ct value (plain line). The dashed curve indicates the polynomial regression curve

[245] ***Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19***
Journal of Medical Virology
Yafang Li, Lin Yao, *et al*.
March 26, 2020
https://onlinelibrary.wiley.com/doi/10.1002/jmv.25786

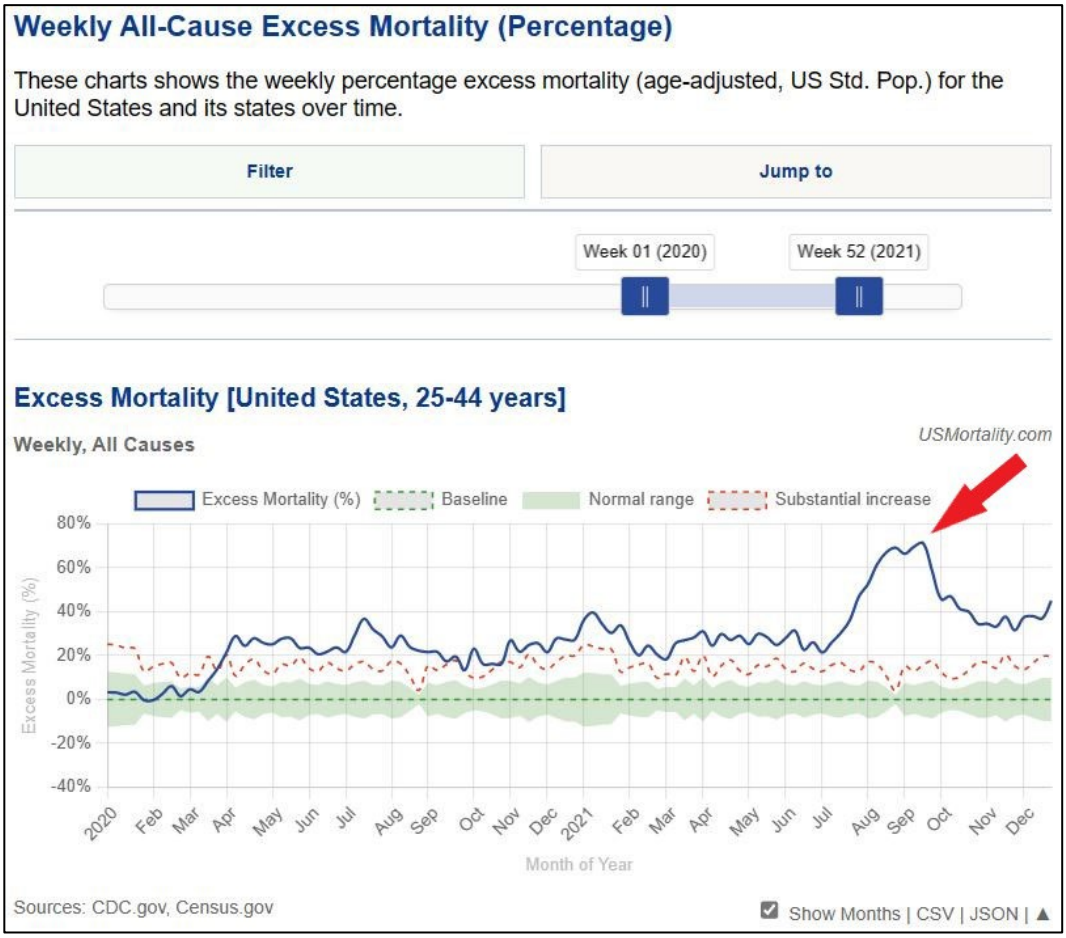
"**Abstract**: In this study, we collected a total of 610 hospitalized patients from Wuhan between February 2, 2020, and February 17, 2020. We reported a potentially high false negative rate of real-time reverse-transcriptase polymerase chain reaction (RT-PCR) testing for SARS-CoV-2 in the 610 hospitalized patients clinically diagnosed with COVID-19 during the 2019 outbreak. We also found that the RT-PCR results from several tests at different points were variable from the same patients during the course of diagnosis and treatment of these patients…"

[246] **ADDED since 2/8/2022**

Weekly All-Cause Excess Mortality (Percentage)

"Reported deaths are taken from CDC's weekly dataset. The baseline is calculated as average of 2015-2019… The excess deaths are calculated as observed deaths minus baseline."
https://www.usmortality.com/excess-mortality/percentage

From July through August of 2021, all-cause excess mortality for Americans aged 25-44 rose to an unprecedented 71%.



[247] **ADDED since 2/8/2022**

Group Life COVID-19 Mortality Survey Report?

Society of Actuaries (SOA) Research Institute
August 2022
https://www.soa.org/4a368a/globalassets/assets/files/resources/research-report/2022/group-life-covid-19-mortality-03-2022-report.pdf

"**Section 1: Purpose of the Survey**: The purpose of this survey was to gather a high-level view of U.S. Group Term Life Insurance mortality results during the COVID-19 pandemic, as compared to prior period baseline mortality results….

2.1 Background

Carriers provided a complete set of monthly Group Life exposures dating back to January 2017, along with all Group Life death claims reported in January 2017 or later. The reported death claims also identified the months of death, i.e., incurred months.

Exposures and deaths during the three-year period of 2017–2019 were used to set baseline mortality expectations. The dataset for this report encompasses all Group Life claims reported to participating carriers as of March 31, 2022…

2.3 Survey Highlights …

Additional highlights include the following:

- Approximately **13% of all reported Group Life claims** with death dates in the pandemic period were determined to have a cause of death of COVID-19…
- Early quarters of the pandemic period (Q2 and Q3 2020) showed the Group Life insured population studied within this survey experienced a lower percentage of excess deaths than the U.S. population. Beginning in the fourth quarter of 2020, **this relationship flipped**, with subsequent quarters indicating higher excess mortality for the Group Life insured population by a percentage difference ranging from 2% to 10% (additive) by quarter

5.4 Age and Sex

For the Age and Sex segments, excess mortality for the pandemic period was split between COVID and non-COVID claims. For example, for the 45–64 age group, the 25.1% COVID and 8.1% Non-COVID total 33% excess mortality, which equates to the 133% A/E ratio since April 2020. Generally, the 65+ age band continues to have lower A/E ratios. However, the bulk of excess mortality for this age group (which includes retirees) was identified as COVID. Cumulative A/E ratios have been similar since April 2020 for the 0–44 and 45–64 age bands, but the recent improvement has been more dramatic for the 0–44 age band after experiencing an extremely high A/E ratio in Q3 2021. A much greater proportion of excess mortality was identified as COVID for the 45–64 age band, whereas **the 0–44 age band has experienced significant non-COVID excess mortality**, as shown in Table 5.6.

Table 5.6
EXCESS MORTALITY BY AGE BAND

Age	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	4/20-3/22	% COVID	% Non-COVID	% Count
0-44	123%	131%	121%	121%	130%	179%	140%	124%	133%	16.4%	17.1%	8%
45-64	119%	124%	129%	131%	116%	162%	144%	139%	133%	25.1%	8.1%	28%
65+	114%	110%	129%	120%	100%	116%	116%	114%	115%	13.7%	1.1%	64%
All[10]	**116%**	**115%**	**129%**	**123%**	**107%**	**134%**	**126%**	**122%**	**121%**	**17.1%**	**4.3%**	**100%**

The greater age band detail in Table 5.7 provides further insight on excess mortality by age. The youngest age bands saw significant improvement in the last two quarters, but the working age population continues to see the **highest A/E ratios**. The overall A/E ratios are similar (but

slightly higher) by amount versus count for age bands below 65. For age bands over 65, A/E ratios tend to be higher by amount than count by approximately 10%."

Table 5.7
EXCESS MORTALITY BY DETAILED AGE BAND

Age	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	4/20-3/22	% COVID	% Non-COVID	% Count
0-24	116%	124%	104%	101%	119%	127%	110%	91%	111%	3.3%	8.1%	2%
25-34	127%	132%	121%	118%	131%	178%	131%	125%	133%	13.3%	19.6%	2%
35-44	123%	134%	128%	129%	133%	200%	156%	136%	142%	23.1%	19.2%	4%
45-54	123%	127%	129%	133%	119%	180%	151%	143%	138%	27.4%	10.8%	9%
55-64	117%	123%	130%	130%	114%	153%	141%	137%	131%	24.0%	6.7%	18%
65-74	117%	115%	133%	130%	108%	131%	125%	122%	122%	18.6%	3.9%	17%
75-84	114%	114%	133%	123%	106%	119%	121%	121%	119%	14.0%	4.6%	20%
85+	112%	103%	124%	111%	92%	104%	105%	103%	107%	10.3%	-3.5%	27%
All[11]	**116%**	**115%**	**129%**	**123%**	**107%**	**134%**	**126%**	**122%**	**121%**	**17.1%**	**4.3%**	**100%**

[248] **ADDED since 2/8/2022**

Graphs and maps: Excess mortality
EuroMOMO
Updated on week 2, 2023
https://www.euromomo.eu/graphs-and-maps#excess-mortality
"EuroMOMO is a European mortality monitoring activity, aiming to detect and measure excess deaths related to seasonal influenza, pandemics and other public health threats.
Official national mortality statistics are provided weekly from the 29 European countries or subnational regions in the EuroMOMO collaborative network, supported by the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO), and hosted by Statens Serum Institut, Denmark."

"**Excess mortality**: Graphs showing the weekly excess deaths (deviation in mortality from the expected level) in the data-providing EuroMOMO partner countries for the past years, all ages and by age groups."

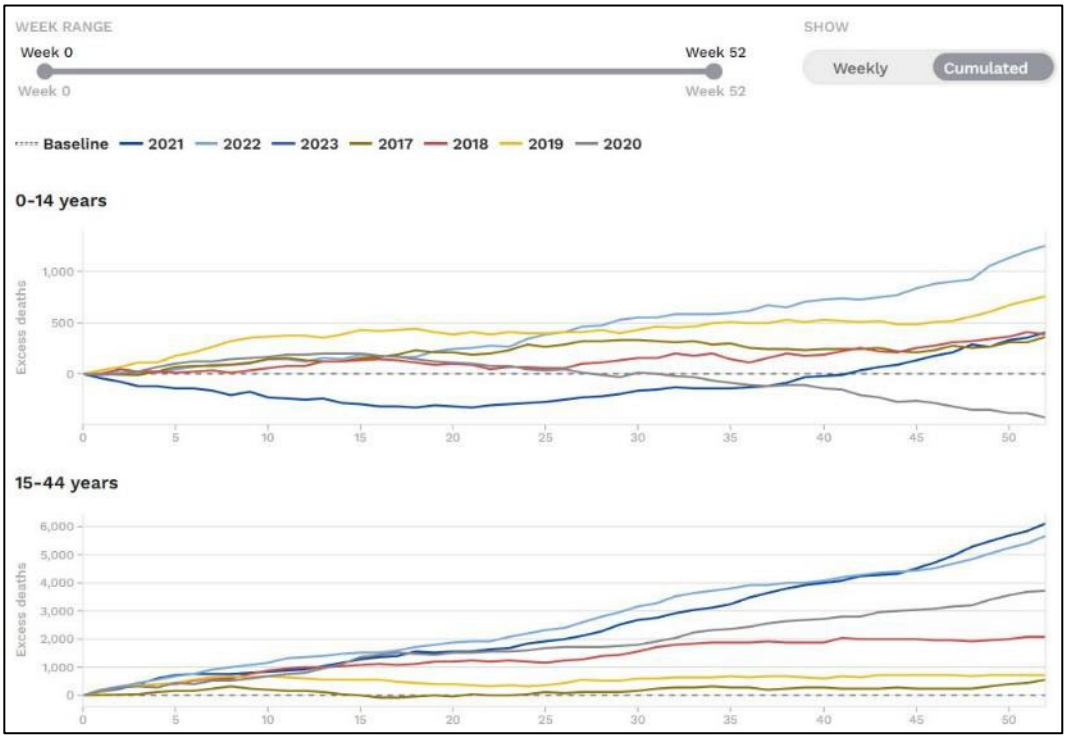
1-14 years (of age)

- **2022** = 1,261
- **2021** = 412
- **2020** = - 419
- **2019** = 762
- **2018** = 386
- **2017** = 367

15-44 years (of age)

- **2022** = 5,707
- **2021** = 6,145
- **2020** = 3,741

- **2019** = 735
- **2018** = 2,083
- **2017** = 568



[249] **ADDED since 2/8/2022**
Japan overage and exiguous deaths dashboard
National Institute of Infectious Diseases, Japan
Figures as of January 9, 2023
https://exdeaths-japan.org/graph/numberof

Excess deaths:

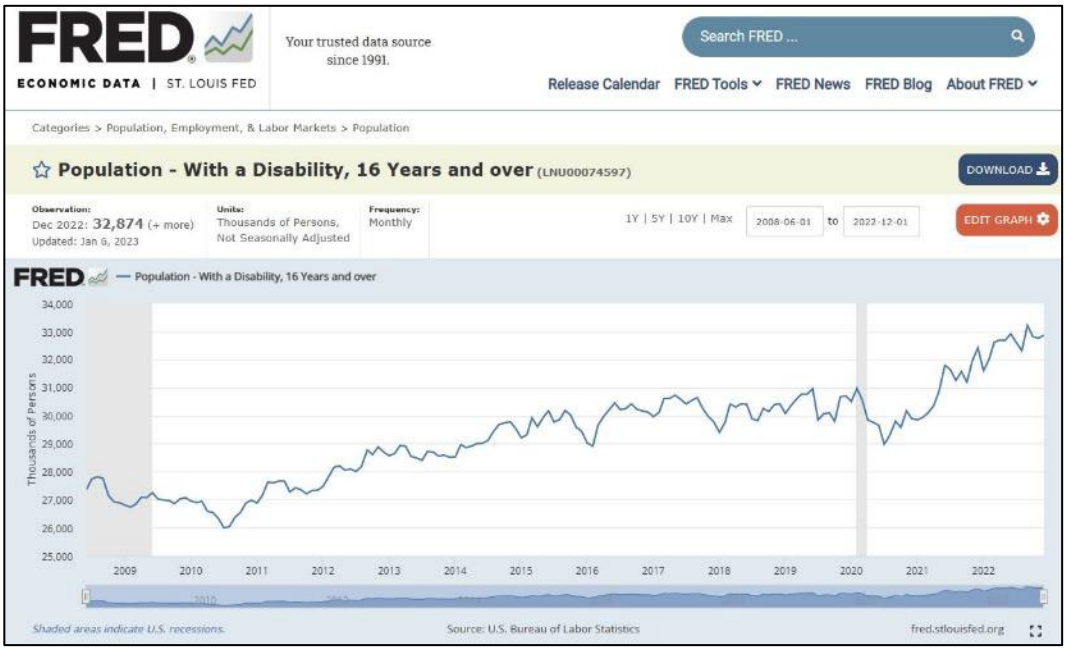
- **JAN to SEPT 2022: 38,003 to 82,684**
- **2021** = 10,762 to 50,479
- **2020** = 268 to 8,526
- **2019** = 971 to 10,845
- **2018** = 4,611 to 20,163
- **2017** = 2,954 to 26,544

Dashboard: Excess deaths from 2022.01 to 2022.09

[250] **ADDED since 2/8/2022**
Population - With a Disability, 16 Years and over
Federal Reserve Bank of St. Louis
Data as of April 3, 2023
https://fred.stlouisfed.org/series/LNU00074597

The number of people in the US who are 1) disabled and 2) 16 years or older grew by **10.0%** between December 2020 and December 2022 [(32,874 – 29.887) / 29.887].

- **December 2015**: 29,447
- **December 2016**: 30,131
- **December 2017**: 29,780
- **December 2018**: 30,426
- **December 2019**: 30,705
- **December 2020**: 29,887
- **December 2021**: 32,420
- **December 2022**: 32,874



[251] **ADDED since 2/8/2022**

Sudden cardiac death in athletes: the Lausanne Recommendations

European Journal of Preventive Cardiology — University of Lausanne, France

Karin Bille, David Figuerias, *et al*.

December 1, 2006

https://academic.oup.com/eurjpc/article/13/6/859/5932831

"**Objectives**: This study reports on sudden cardiac death (SCD) in sport in the literature and aims at achieving a generally acceptable preparticipation screening protocol (PPSP) endorsed by the consensus meeting of the International Olympic Committee (IOC).

Background: The sudden death of athletes under 35 years engaged in competitive sports is a well-known occurrence; the incidence is higher in athletes (~ 2/100 000 per year) than in non-athletes (2.5:1), and the cause is cardiovascular in over 90%.

Methods: A systematic review of the literature identified causes of SCD, sex, age, underlying cardiac disease and the type of sport and PPSP in use. Methods necessary to detect pre-existing cardiac abnormalities are discussed to formulate a PPSP for the Medical Commission of the IOC.

Results: SCD occurred in **1101 (1966–2004)** reported cases in athletes under 35 years, 50% had congenital anatomical heart disease and cardiomyopathies and 10% had early-onset atherosclerotic heart disease. Forty percent occurred in athletes under 18 years, 33% under 16 years; the female/male ratio was 1/9. SCD was reported in almost all sports; most frequently involved were soccer (30%), basketball (25%) and running (15%). The PPSP were of varying quality and content."

Note: The citations below are presented in reverse, chronological order.

[252] **ADDED since 2/8/2022**
Is there a Link between the 2021 COVID-19 Vaccination Uptake in Europe and 2022 Excess All-Cause Mortality?
Western Norway University of Applied Sciences
Jarle Aarstad and Olav Andreas Kvitastein
February 21, 2023
https://www.preprints.org/manuscript/202302.0350/v1

"**Abstract**: We primarily study a possible link between 2021 COVID-19 vaccination uptake in Europe and monthly 2022 excess all-cause mortality, i.e., mortality higher than before the pandemic. Analyses of 31 countries weighted by population size show that all-cause mortality during the first nine months of 2022 increased more the higher the 2021 vaccination uptake; **a one percentage point increase in 2021 vaccination uptake was associated with a monthly mortality increase in 2022 by 0.105 percent** (95% CI, 0.075-0.134). When controlling for alternative explanations, the association remained robust, and we discuss the result emphasizing causality as well as potential ecological fallacy. Also, the study shows that 2021 all-cause mortality was lower the higher the vaccination uptake, but this association became non-significant when controlling for alternative explanations."

[253] **ADDED since 2/8/2022**
Forgotten "Primum Non Nocere" and Increased Mortality after Covid-19 Vaccination
Stationary Coslmology Initiative, Slovenia
Amrit Šorli, Tomaž Makovec, Živan Krevel, and Rado Gorjup
February 13, 2023
https://www.preprints.org/manuscript/202301.0204/v3

"**Background**: The main impetus behind the worldwide Covid-19 vaccination campaign in 2021 was to reduce the mortality attributed to SARS-CoV-2 infection in the preceding year. Nevertheless, rigorous analyses of the mortality benefits conferred by this massive vaccination effort have been lacking.

Methods: Statistics offers us an essential methodological approach for measuring the impacts of Covid-19 vaccination on public health. The mathematical relation between vaccinated-alive groups can be repeated between vaccinated-dead groups with relatively high statistical reliability because of the large population numbers involved. This method also confers greater statistical usefulness because it eliminates the Simpson effect.

Results: Calculations were performed for each of the following five four-week intervals: weeks 35-38 (2021), weeks 39-42 (2021), weeks 43-46 (2031), weeks 47-50 (2021), and weeks 51(2021)-2(2022). The results obtained confirm that the mortality of the vaccinated coronavirus-infected groups was **14.5% higher** on average than the mortality of non-vaccinated coronavirus-infected groups.

Conclusions: Vaccinated infected groups appear to have higher average mortality than their non-vaccinated infected counterparts. The findings suggest the legitimacy of extending the statistic between vaccinated living and vaccinated dead individuals for different age groups. Calculating the impact of Covid-19 vaccination on the mortality rate is a necessary step toward satisfying the first principle of medicine: 'Primum non nocere', 'Do no harm'."

[254] **ADDED since 2/8/2022**

Video (1h06m): Independent SAGE (Scientific Advisory Group for Emergencies): Weekly Briefing with Stuart McDonald

McDonald is Deputy Chair of the Continuous Mortality Investigation (CMI) and Co-Chair of the COVID-19 Actuaries Response group

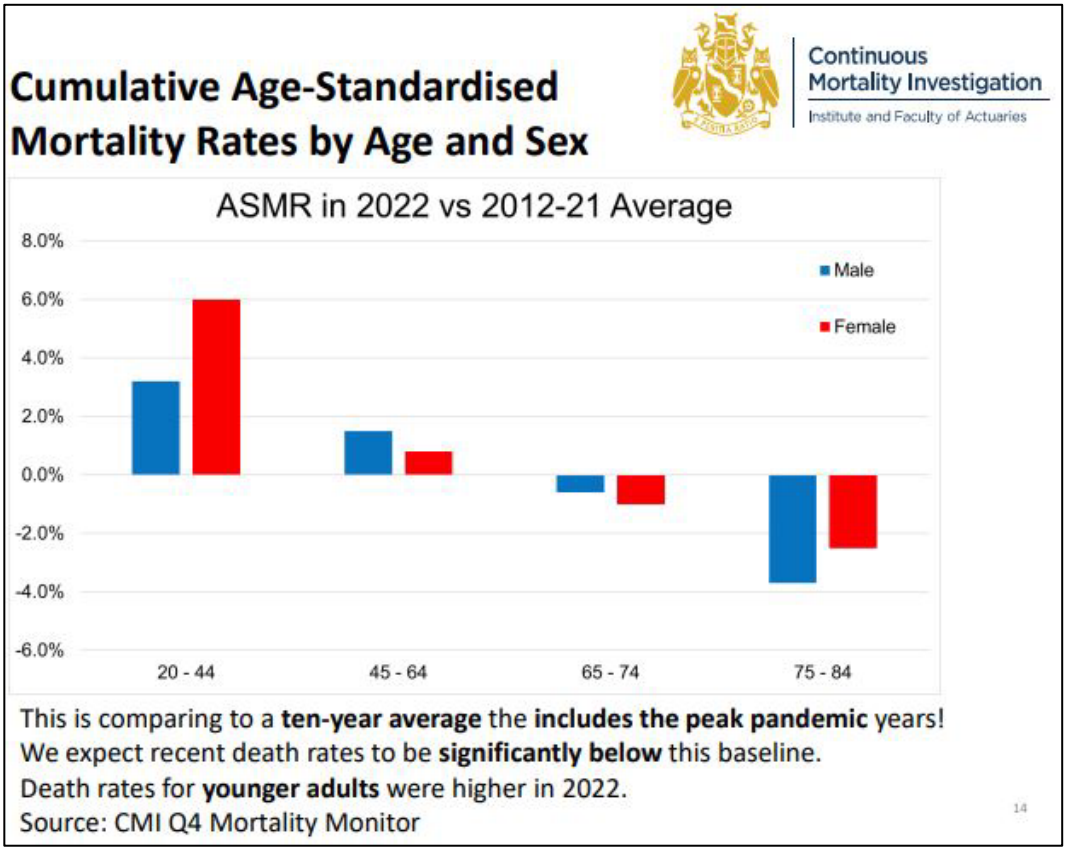
January 27, 2023

https://www.independentsage.org/weekly-briefing-27th-jan-2023/

McDonald (35:30m): "If we look on the next slide [*below*], this is from the latest CMI quarterly analysis. Now this quarterly analysis pre-dates the pandemic, and it's mostly used by actuaries… This is a 10-year average. It's including 2020. It"s including 2021. So every age group ought to have mortality a long way below this benchmark.But you can actually see that although the oldest groups are experiencing mortality below the 10-year average, the younger groups, particularly females, are experiencing death rates that are **higher than the 10-year average** that includes the two pandemic years. So we're really seeing, quite pronounced, relative excess mortality."

Prof. Christina Pagel: "So that's quite shocking though, really, isn't it? That we're seeing that, particularly in younger adults."

McDonald: "Yes. I would absolutely agree… It really feels like it's the young adults that are being most affected by the indirect impacts of the pandemic."



[255] **ADDED since 2/8/2022**

Deaths registered weekly in England and Wales, provisional: week ending 23 December 2022

Office for Natinoal Statistics, UK
January 5, 2023
https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregisteredweeklyinenglandandwalesprovisional/weekending23december2022

"**1. Main points**

- In the week ending 23 December 2022 (Week 51), 14,530 deaths were registered in England and Wales; 429 of these deaths mentioned "novel coronavirus (COVID-19)", accounting for 3.0% of all deaths…
- The number of deaths was above the five-year average in private homes (37.5% above, 1,120 excess deaths), hospitals (18.8% above, 1,031 excess deaths), care homes (10.5% above; 282 excess deaths) and other settings (7.0% above, 61 excess deaths) in Week 51 in England and Wales…"

Table 1: Deaths registered in England and Wales, week ending 23 December 2022 (Week 51 2022)

Week 51 2022	England and Wales	England	Wales
Total deaths (all causes)	14,530	13,530	961
Total deaths above 5 year average	2,493	2,272	206
Percentage change compared to 5-year average (2016 to 2019 and 2021)	20.7%	20.2%	27.3%
Deaths involving COVID-19	429	397	32
Percentage of deaths involving COVID-19	3.0%	2.9%	3.3%

[256] **ADDED since 2/8/2022**

Video (2m): New report on UK excess deaths

Sky News, UK
January 5, 2023
https://twitter.com/jamesmelville/status/1611034393702694924

Reporter: "Today, the data from the Office of National Statistics gives us a snapshot of the number of people we expect to die in any given period… and how many people are actually dying. So these are 'excess deaths'…

So, we have 14,530 people who died in England and Wales in the week ending 23 December… When you compare that to weeks in previous years, that means roughly two-and-a-half thousand more people died than expected…

Over the last 6 months, the total number of excess deaths is over 30,000 in England and Wales. There have been exactly 8,000 deaths due to COVID in that period, and if we exclude those from the total, it means there's been an extra **22,040** deaths not caused by COVID in the past six months alone, equivalent to **848** per week. We don't know what is driving those excess deaths."

[257] **ADDED since 2/8/2022**

The Devil's Advocate: An Exploratory Analysis of 2022 Excess Mortality: What is causing excess deaths: Covid, long-covid, lockdowns, healthcare or the vaccines?
Queen Mary University of London
Norman Fenton and Martin Neil
December 14, 2022
https://wherearethenumbers.substack.com/p/the-devils-advocate-an-exploratory

"Igor Chudov got in contact recently asking us to fact-check his analysis on the world-wide link between vaccinations and excess deaths. His substack gives a thorough description of his results, but basically it wasn't good news for the covid-19 vaccines and worse news about their effects on mortality…

So, we downed tools on other projects and decided to look at the data to see if we could repeat the analysis and also broaden the hypotheses being tested. After all, blaming the vaccines is a pretty big claim to make. We therefore wanted to act as the 'Devil's Advocate' and ask whether there was evidence to support ALTERNATIVE causes of excess deaths, NOT the vaccination programme…

The alternative hypotheses to test are somewhat obvious:

- Covid-19 occurring in 2022 causing undiagnosed covid deaths in 2022
- So-called long-covid contracted in 2020/21 causing death in 2022
- Stringency of lockdown measures in 2020/21 causing additional deaths in 2022

Healthcare quality influencing or mitigating excess deaths

And finally, we need to also include….

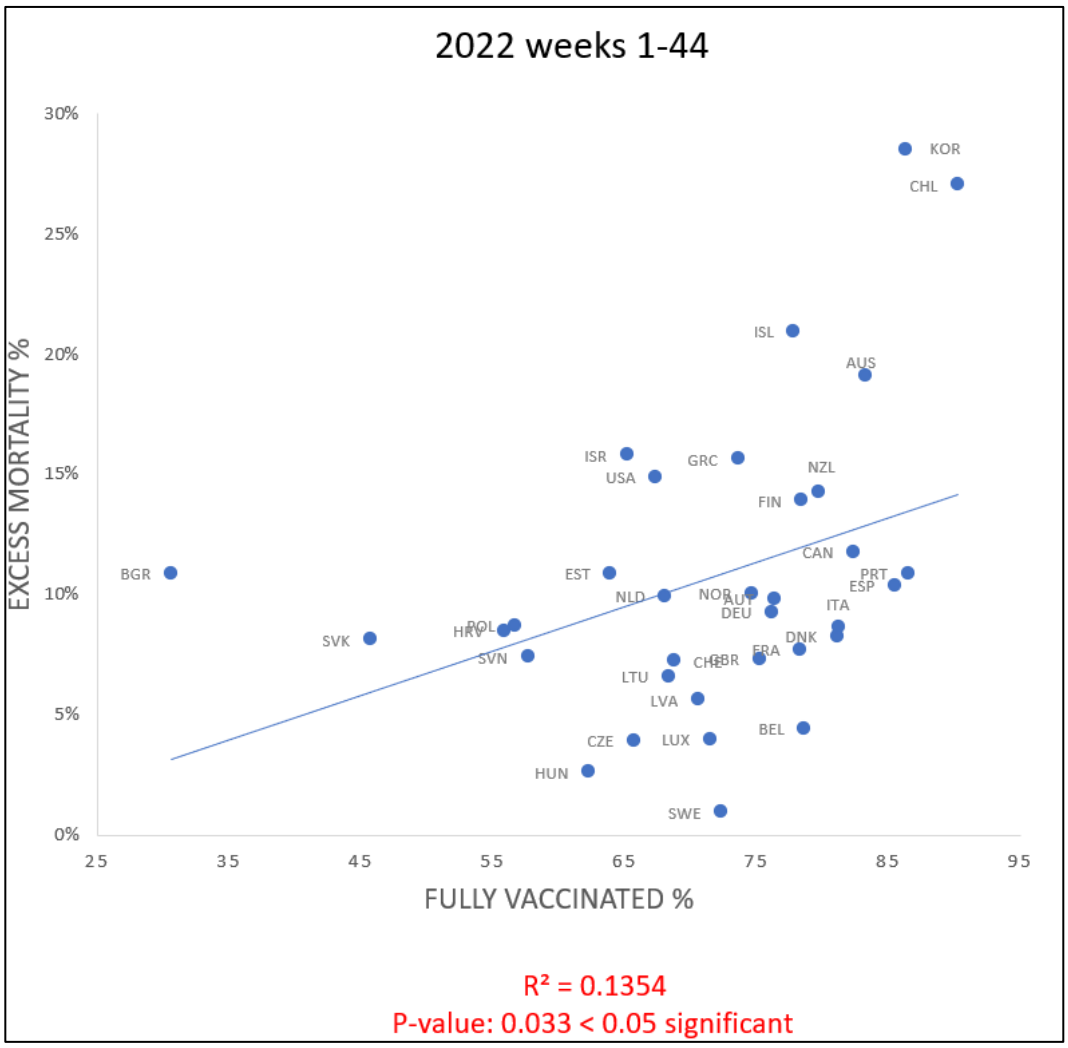
- The covid vaccinations administered in late-2020 and 2021 are causing excess deaths in 2022

What can we conclude then from our EXPLORATORY analysis:

- Clearly the surge in Covid-19 and its effect on excess deaths shows the vaccines are not effective. This looks self-evident and this isn't news.
- There is no evidence to support long-covid as a cause of excess deaths.
- There is weak evidence of the negative effect of lockdown measures (see the video).

- Healthcare quality looks to be irrelevant, but we are not satisfied we have good metrics for this.
- There is a clear signal that **the vaccination programme is causing**, at least, **some of the excess death rate**. With this data the vaccines don't look to be safe.

How long this run of excess deaths lasts is an unknown and remains a frightening prospect. Whether the effects of the vaccination programme persist we do not know, but the evidence for a plausible biological mechanism connecting the vaccines and sudden deaths is now widely accepted.



[258] **ADDED since 2/8/2022**
The WHO estimates of excess mortality associated with the COVID-19 pandemic
Nature — World Health Organization
William Msemburi, Ariel Karlinsky, *et al*.
December 14, 2022
https://www.nature.com/articles/s41586-022-05522-2

"**Abstract**: … Beyond what is directly attributable to it, the pandemic has caused extensive collateral damage that has led to losses of lives and livelihoods. Here we report a

comprehensive and consistent measurement of the impact of the COVID-19 pandemic by estimating excess deaths, by month, for 2020 and 2021. We predict the pandemic period all-cause deaths in locations lacking complete reported data using an overdispersed Poisson count framework that applies Bayesian inference techniques to quantify uncertainty. We estimate **14.83 million excess deaths globally**, 2.74 times more deaths than the 5.42 million reported as due to COVID-19 for the period."

[259] **ADDED since 2/8/2022**

Japan's H1 excess mortality highest since Covid pandemic

Healthworld from The Economic Times, India
IANS agency
October 9, 2022
https://health.economictimes.indiatimes.com/news/diagnostics/japans-h1-excess-mortality-highest-since-covid-pandemic/94738623

"The number of excess deaths in Japan was estimated to have reached between 17,000 and 46,000 in the first six months of the year, the highest figure since the COVID pandemic began in early 2020…

According to statistics from the ministry and Kyodo News, Japan's total number of deaths during the six-month period came in at 777.000, and more than 12,800 people died from COVID infiections, Kyodo News reported.

Experts believed that apart from direct deaths due to COVID, the increase in excess mortality can also be attributed to deaths indirectly caused by the pandemic, citing **deaths from other diseases due to the inability to access medical institutions** and **worsened chromic illnesses due to lifestyle changes**, as well as **suicides** due to economic hardships, the media reported."

[260] **ADDED since 2/8/2022**

Excess mortality in Germany 2020-2022

University of Regensburg and Osnabruck University, Germany
Christof Kuhbandner and Matthias Reitzner
August 2022
https://www.researchgate.net/publication/362777743_Excess_mortality_in_Germany_2020-2022

"**Abstract**: … In 2020, the observed number of deaths was close to the expected number with respect to the empirical standard deviation. By contrast, in 2021, the observed number of deaths was **two empirical standard deviations above the expected number**. The high excess mortality in 2021 was almost entirely due to an increase in deaths in the age groups between 15 and 79 and started to accumulate only from April 2021 onwards. A similar mortality pattern was observed for stillbirths with an increase of about 11 percent in the second quarter of the year 2021.

Something must have happened in April 2021 that led to a sudden and sustained increase in mortality in the age groups below 80 years, although no such effects on mortality had been observed during the COVID-19 pandemic so far…

Conclusion: … As a starting point for further investigations explaining this mortality patterns, we compared the excess mortality to the number of reported COVID-19 deaths and the

number of COVID-19 vaccinations. This leads to several open questions, the most important being the **covariation between the excess mortality and the COVID-19 vaccinations**."

[261] **ADDED since 2/8/2022**

Why Are All-Cause Excess Deaths in the Under-45s So Much Higher This Year Than at the Height of the Pandemic?

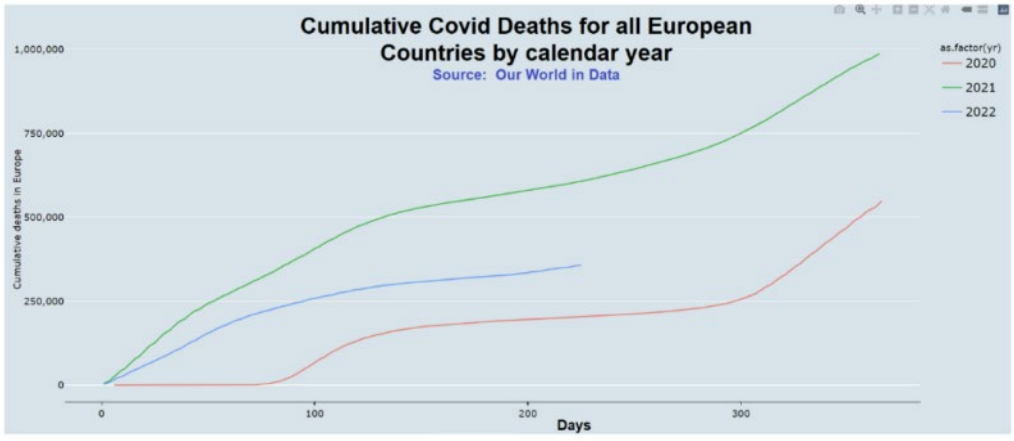
Daily Sceptic
Nick Rendell
August 15, 2022
https://dailysceptic.org/2022/08/15/why-are-all-cause-excess-deaths-in-the-under-45s-so-much-higher-this-year-than-at-the-height-of-the-pandemic/

"Euromomo tells us that by week 31 of 2022 there have been 3,360 excess all-cause deaths of people under 45 across the Euromomo contributing countries. This compares with 1,640 excess all-cause deaths by week 31 in 2020 in the under-45s, an increase of 105%. All-cause, of course, includes Covid deaths…

Across the contributing Euromomo countries, all-cause, all-age excess mortality is virtually the same at this stage of the year for 2020, 2021 and 2022. Intuitively, that seems strange. 2020 was the year of a once-in-a-century pandemic hitting a naïve population. Since then, we've vaccinated getting on for 90% of the population multiple times. Evolution has been kind to us and the original Wuhan strain is now the relative pussycat that is Omicron. We've got masses of natural immunity – is that a thing anymore? I forget. Anyway, we should be in a vastly better place than in 2020, and yet we're not…

Another odd thing I've only recently noticed is that cumulative Covid deaths across Europe according to Our World in Data are higher in 2022 year to date than they were at this stage in 2020. How can that be? I don't want to labour the point, but Omicron is more benign, there's loads of natural immunity and 90% of the population has been vaccinated. What's going on? **How come it was a disaster in 2020 and now, in 2022, apparently more people are dying and no one mentions it?**"

Fig 6



[262] **ADDED since 2/8/2022**

Deaths with unknown causes now Alberta's top killer: province

CTV News Calgary
Nicole Di Donato
July 6, 2022
https://calgary.ctvnews.ca/deaths-with-unknown-causes-now-alberta-s-top-killer-province-1.5975536

> "Alberta is reporting an unprecedented increase in ill-defined and unknown causes of death in 2021…
>
> In 2021, **ill-defined and unknown causes of death** snagged the first spot with 3,362, up from 1,464 in 2020 and 522 the year before that, according to statistics from the Government of Alberta.
>
> The unknown causes of death category only began appearing on the list in 2019 — there is no record of it ranking before then, dating back to 2001…
>
> COVID-19 deaths increased to 1,950 last year from 1,084 in 2020 when the pandemic began.
>
> 'COVID still is quite high up there as we expected. Unfortunately, we haven't been able to actually eliminate COVID deaths in the province, despite our availability of vaccines. So, that's a bit disappointing,' Gregson said."

[263] **ADDED since 2/8/2022**

Non-COVID Excess Deaths, 2020-21: Collateral Damage of Policy Choices?

National Bureau of Economic Research
Casey B. Mulligan and Robert D. Arnott
June 2022
https://www.nber.org/system/files/working_papers/w30104/w30104.pdf

> "**Abstract**: From April 2020 through at least the end of 2021, Americans died from non-Covid causes at an **average annual rate 97,000 in excess of previous trends**. Hypertension and heart disease deaths combined were elevated 32,000. Diabetes or obesity, drug-induced causes, and alcohol-induced causes were each elevated 12,000 to 15,000 above previous (upward) trends. Drug deaths especially followed an alarming trend, only to significantly exceed it during the pandemic to reach 108,000 for calendar year 2021. Homicide and motor-vehicle fatalities combined were elevated almost 10,000. Various other causes combined to add 18,000. While Covid deaths overwhelmingly afflict senior citizens, absolute numbers of non-Covid excess deaths are similar for each of the 18-44, 45-64, and over-65 age groups, with essentially no aggregate excess deaths of children. Mortality from all causes during the pandemic was elevated 26 percent for workingage adults (18-64), as compared to 18 percent for the elderly. Other data on drug addictions, nonfatal shootings, weight gain, and cancer screenings point to a historic, yet largely unacknowledged, health emergency."

[264] **ADDED since 2/8/2022**

Mortality in Cyprus Over the Period 2016-2021

Cureus

Demetris Avraam, Eleftheria C. Economidou, *et al*.

April 20, 2022

https://www.cureus.com/articles/91317-mortality-in-cyprus-over-the-period-2016-2021

"**Background**: Mortality in the general population is one of the most robust measures used to examine epidemiological trends over time and especially over periods of public health crises such as the current coronavirus disease 2019 (COVID-19) pandemic.

Methodology: In this study, we analyzed information reported by the Cyprus Ministry of Health to the European Statistical Office (Eurostat), which includes weekly all-cause mortality over the period 2016-2021. In addition, we used data collected by the European Centre for Disease Prevention and Control regarding daily reported COVID-19 cases and COVID-19-related deaths.

Results: Based on our data analysis, we observed a substantial increase of 9.7% in all-cause mortality in Cyprus in 2021 compared to 2020, with an **overall mortality increase of 16.5% in 2021** compared to the mean mortality of the previous five years. Particularly, we documented a sharp increase over the third and the fourth quarters of the year 2021.

Conclusions: The substantial increase in mortality in Cyprus in 2021 is **not entirely explained by COVID-19 deaths** and is parallel to the concurrent vaccination campaign. This concerning observation should be comprehensively investigated by the National and European public health authorities to identify and address the underlying causes."

[265] **ADDED since 2/8/2022**

COVID-19 and All-Cause Mortality Data by Age Group Reveals Risk of COVID Vaccine-Induced Fatality is Equal to or Greater than the Risk of a COVID death for all Age Groups Under 80 Years Old as of 6 February 2022)

Kathy Dopp and Stephanie Seneff

February 13, 2022

https://vixra.org/pdf/2202.0084v1.pdf

"**Abstract**: As of 6 February 2022, based on publicly available official UK and US data, all age groups under 50 years old are at greater risk of fatality after receiving a COVID-19 inoculation than an unvaccinated person is at risk of a COVID-19 death. All age groups under 80 years old have virtually no benefit from receiving a COVID-19 inoculation, and the younger ages incur significant risk. This analysis is conservative because it ignores the fact that inoculation-induced adverse events such as thrombosis, myocarditis, Bell's palsy, and other vaccine-induced injuries can lead to shortened life span. When one takes into consideration the fact that there is approximately a 90% decrease in risk of COVID-19 death if early treatment is provided to all symptomatic high-risk persons, one can only conclude that mandates of COVID-19 inoculations are ill-advised. Considering the emergence of antibody-resistant variants like Delta and Omicron, for most age groups COVID-19 vaccine inoculations result in **higher death rates** than COVID-19 does for the unvaccinated…

Conclusion: … According to the data analysis presented in this paper, **all age cohorts under 50 years old are at greater risk (from 5 to 51 times higher) of vaccine-induced fatality**

within the same or subsequent month of receiving a COVID-19 inoculation than they are at risk of a COVID-19 death within 60 days of a positive test if unvaccinated. All age cohorts have less than ¼ of 1% benefit of absolute risk reduction of a COVID-19 death from receiving a COVID-19 inoculation. Children under age 18 years have 51 times higher chance of fatality after a COVID inoculation than risk of dying from COVID if unvaccinated… This analysis is conservative because it ignores the inoculation-induced risk increases of later fatalities and shortened life spans from thrombosis, myocarditis, Bell's palsy, and other known vaccine-induced injuries and ignores the 90% or more decreases in risk of COVID-19 death if early, effective treatments were provided to all symptomatic high-risk persons [5,9]. Mandates of COVID inoculations are ill-advised because the alleged vaccines result in higher death rates than COVID itself."

[266] ***OneAmerica CEO says death rates among working-age people up 40%***
Insurance Forums
Insurance Forums Staff
January 3, 2022
https://insurance-forums.com/life-insurance/oneamerica-ceo-says-death-rates-among-working-age-people-up-40/
Video (2m): https://www.bitchute.com/video/W1dIuHJMvaf9/

Scott Davison, OneAmerica CEO: ""We're seeing right now the highest death rates we've ever seen in the history of this business, and not just at OneAmerica. The data is consistent across every player in that business.

Now this is primarily working-age people, 18 to 64…

Now what we saw just in the 3rd quarter, and we're seeing it continue into the 4th quarter, is that **death rates are up 40%** over what they were pre-pandemic [*emphasis added*].

Just to give you an idea of how bad that is, a three sigma or a 1-in-200-year catastrophe would be a 10% increase over pre-pandemic. So, 40% is just unheard of. And what the data is showing us is that the deaths that are being reported as COVID deaths greatly understate the actual death losses among working-age people from the pandemic. It may not all be COVID on their death certificate, but deaths are up just huge, huge numbers."

[267] **ADDED since 2/8/2022**
Life insurance death claims shoot 41%, up 3.5x in 2021
Fortune India
Avneet Kaur
December 30, 2021
https://www.fortuneindia.com/enterprise/life-insurance-death-claims-shoot-41-up-35x-in-2021/106563

"The life insurance industry is likely to post a 200-300% increase in claims this year, hurting the profitability of most insurers…

Latest data from Insurance Regulatory and Development Authority of India (IRDAI) shows the death claims rose by 41% in FY21 to ₹41,958 crore. Whereas, earlier in FY20, the death claims rose by 11% to ₹29,793 crore."

[268] ***Latest statistics on England mortality data suggest systematic mis-categorisation of vaccine status and uncertain effectiveness of Covid-19 vaccination***
University of London
Martin Neil, Norman Elliott Fenton, *et al*.
December 3, 2021
https://www.researchgate.net/publication/356756711_Latest_statistics_on_England_mortality_data_suggest_systematic_mis-categorisation_of_vaccine_status_and_uncertain_effectiveness_of_Covid-19_vaccination

"**9. Summary and Conclusions**: … At first glance the data suggest that, in each of the older age groups, all-cause mortality is lower in the vaccinated than the unvaccinated. In the 10-59 age group all-cause mortality is higher among the vaccinated, but this group is likely confounded by age since it is far too wide for the data provided to be sufficient to draw any firm conclusions.

However, despite this apparent evidence to support vaccine effectiveness - at least for the older age groups - on closer inspection of this data, this conclusion is cast into doubt. That is because we have shown a range of fundamental inconsistencies and flaws in the data. Specifically:

- In each group the non-Covid mortality rates in the three different categories of vaccinated people fluctuate in a wild, but consistent way, far removed from the expected historical mortality rates.
- Whereas the non-Covid mortality rate for unvaccinated should be consistent with historical mortality rates (and if, anything slightly lower than the vaccinated non-Covid mortality rate) it is not only higher than the vaccinated mortality rate, but it is far higher than the historical mortality rate.
- In previous years each of the 60-69, 70-79 and 80+ groups have mortality peaks at the same time during the year (including 2020 when all suffered the April Covid peak at the same time). Yet in 2021 each age group has non-Covid mortality peaks for the unvaccinated at a different time, namely the time that vaccination rollout programmes for those cohorts reach a peak.
- The peaks in the Covid mortality data for the unvaccinated are inconsistent with the actual Covid wave…

Absent any other better explanation Occam's razor would support our conclusions. In any event, the ONS [*UK Office for National Statistics*] data provide **no reliable evidence that the vaccine reduces all-cause mortality** [*emphasis added*]."

[269] ***FDA report finds all-cause mortality higher among vaccinated***
Arutz Sheva (Israel)
David Rosenberg
November 17, 2021
https://www.israelnationalnews.com/News/News.aspx/317091

"The clinical trials of Pfizer's coronavirus vaccine found that the all-cause mortality rate of the vaccinated group was higher than that of the control group, months after the trials were launched, according to a recently released FDA report.

According to the report, which was released by the US Food and Drug Administration to provide background information on its August 2021 decision to grant full approval for the Pfizer-BioNTech coronavirus vaccine after offering limited emergency authorization of use in last December, six months after the vaccine's clinical trial began, the total number of deaths reported in the vaccinated group was nearly one-quarter higher than the number of deaths in the placebo group…

The relative difference in all-cause deaths between the two cohorts amounts to 23.5%...

The total number of serious adverse events reported among the placebo and vaccine group were comparable, with 103 events reported among the vaccine group and 117 among the control group, though a break-down and comparison of serious adverse events was not provided."

[270] **ADDED since 2/8/2022**

Health insurers see huge surge in non-Covid claims

The Times of India
Mayur Shetty & Sumitra Debroy
October 25, 2021
https://timesofindia.indiatimes.com/business/india-business/health-insurers-see-huge-surge-in-non-covid-claims/articleshow/87245762.cms

"MUMBAI: Even as Covid hospitalisations have dropped from peak levels, insurance companies are witnessing a massive surge in non-Covid claims. WHiel there is a lag in capturing trends, isnurers say that there has been a significant jump from September in non-Covid hospitalisations…

According to Dr Dev Pahlajani, head of interventional cardiology at Breach Candy Hospital in Mumbai, incidences of acute coronary syndrome, sudden heart attacks and cardiac arrest have **gone up 40% in the last six to eight months**. 'There's a surge in circulatory conditions which warrants a close evaluation,' he said.

'People have lost jobs, their source of income and probably sat idle at home for months. Those factors combined with lack of exercise can build up the stress levels, putting them at risk of heart conditions,' said Dr. Pahlajani. He added that people have been missing out on routine checks on sugar and blood pressure levels due to the pandemic."

[271] **ADDED since 2/8/2022**

Impact of COVID-19 on excess mortality, life expectancy, and years of life lost in the United States

PLOS One — Western University, Canada
Eunice Y.S. Chan, Davy Cheng, and Janet Martin
September 1, 2021
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0256835

"**Abstract**: This paper quantifies the net impact (direct and indirect effects) of the pandemic on the United States population in 2020 using three metrics: excess deaths, life expectancy, and total years of life lost. The findings indicate there were 375,235 excess deaths, with 83% attributable to direct, and **17% attributable to indirect effects of COVID-19** [*i.e., 63,790 = 375,235 * 0.17*]. The decrease in life expectancy was 1.67 years, translating to a reversion of

14 years in historical life expectancy gains. Total years of life lost in 2020 was 7,362,555 across the USA (73% directly attributable, 27% indirectly attributable to COVID-19), with considerable heterogeneity at the individual state level."

[272] **ADDED since 2/8/2022**

Research Letter: *All-Cause Excess Mortality and COVID-19–Related Mortality Among US Adults Aged 25-44 Years, March-July 2020*

JAMA — Yale School of Medicine
Jeremy Samuel Faust, Harlan M. Krumholz, *et al*.
December 16, 2020
https://jamanetwork.com/journals/jama/fullarticle/2774445

"**Results**: … Among adults aged 25 to 44 years, 4535 COVID-19 deaths were recorded, accounting for **38%** (95% CI, 32%-48%) of the measured excess mortality…

Discussion: The COVID-19 pandemic was associated with increases in all-cause mortality among US adults aged 25 to 44 years from March through July 2020. In 3 HHS regions, COVID-19 deaths were similar to or exceeded unintentional opioid overdoses that occurred during several corresponding months of 2018."

[273] **ADDED since 2/8/2022**

Non–COVID-19 excess deaths by age and gender in the United States during the first three months of the COVID-19 pandemic

Public Health — University of Illinois
S.H. Jacobson and J.A. Jokela
October 10, 2020
https://www.sciencedirect.com/science/article/pii/S0033350620304467

"**Objectives**: The first three months of the COVID-19 pandemic has disrupted healthcare systems, creating an environment by which deaths have occurred that are not directly due to COVID-19, but have occurred owing to the healthcare and societal environment resulting from COVID-19. The objective of this research is to quantify such excess deaths, partitioned by age group and gender…

Discussion: The data do not explain why there is a statistically significant increase in expected 2020 non–COVID-19 weekly deaths compared with the expected hybrid 2019 weekly deaths. Czeisler et al.6 discuss delays or avoidance of non–COVID-19 medical care during the pandemic, which could contribute to excess deaths beyond those attributed to COVID-19…

The key takeaway from this analysis is that excess deaths across multiple age and gender cohorts occurred beyond what has been attributed to COVID-19. These excess deaths indicate that people across many age and gender cohorts have died unexpectedly. Over the ensuing months, possible explanations for such excess deaths may become more apparent."

COVID-19 Vaccines, Manufacturers, and the FDA

CDC/FDA Definitions of 'Vaccine' and Gene Therapy

[274] ***CDC Emails: Our Definition of Vaccine is "Problematic"***
Techno Fog
November 2, 2021
https://technofog.substack.com/p/cdc-emails-our-definition-of-vaccine

"The CDC caused an uproar in early September 2021, after it changed its definitions of 'vaccination' and 'vaccine.' For years, the CDC had set definitions for vaccination/vaccine that discussed immunity. This all changed on September 1, 2021.

The prior CDC Definitions of Vaccine and Vaccination (August 26, 2021):

> **Vaccine**: A product that stimulates a person's immune system to **produce immunity** to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose.
>
> **Vaccination**: The act of introducing a vaccine into the body to **produce immunity** to a specific disease.

The CDC Definitions of Vaccine and Vaccination since September 1, 2021:

> **Vaccine**: A preparation that is used to stimulate the body's immune response against diseases. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.
>
> **Vaccination**: The act of introducing a vaccine into the body to **produce protection** from a specific disease…

To many observers, it appeared the CDC changed the definitions because of the waning effectiveness of the COVID-19 vaccines. For example, the effectiveness of the Pfizer vaccine falls over time, with an Israeli study reported in August 2021 as showing the vaccine being "only 16% effective against symptomatic infection for those individuals who had two doses of the shot back in January.

Internal CDC E-Mails

CDC emails we obtained via the Freedom of Information Act reveal CDC worries with how the performance of the COVID-19 vaccines didn't match the CDC's own definition of 'vaccine'/'vaccination'…"

***Note**: In the following 6m video, Peter Doshi, Senior Editor at the British Medical Journal, also provides Merriam-Webster's definition of '**vaccine'** from 2006 to January 18, 2021: "a preparation of killed microrganisms, living attenuated organisms, or living fully virulent organisms that is administered to **produce or artificially increase immunity** to a particular disease."*
https://www.bitchute.com/video/OvM5meOXk9o/

[275] **ADDED since 2/8/2022**
What is Gene Therapy?
US Food & Drug Administration
July 25, 2018
https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

> "Human gene therapy seeks to modify or manipulate the expression of a gene **or** to alter the biological properties of living cells for therapeutic use…
>
> There are a variety of types of gene therapy products, including:
>
> - **Plasmid DNA**: Circular DNA molecules can be genetically engineered to carry therapeutic genes into human cells.
> - **Viral vectors**: Viruses have a natural ability to deliver genetic material into cells, and therefore some gene therapy products are derived from viruses. Once viruses have been modified to remove their ability to cause infectious disease, these modified viruses can be used as vectors (vehicles) to carry therapeutic genes into human cells…"

COVID-19 Vaccine Manufacturers

Legal Immunity from Liability

Note: The citations below are presented in reverse, chronological order.

[276] ***Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness [PREP] Act for Medical Countermeasures Against COVID-19***
US Federal Register
September 14, 2021
https://www.federalregister.gov/documents/2021/09/14/2021-19790/ninth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical

> "The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide **liability immunity** to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures [*emphasis added*] (Covered Countermeasures), except for claims involving 'willful misconduct' as defined in the PREP Act."

[277] ***HHS Amends PREP Act Declaration to Increase Workforce Authorized to Administer COVID-19 Vaccines***
U.S. Department of Health & Human Services
January 28, 2021
https://www.hhs.gov/about/news/2021/01/28/hhs-amends-prep-act-declaration-increase-workforce-authorized-administer-covid-19-vaccines.html

> "The U.S. Department of Health and Human Services (HHS) today issued a fifth amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to add additional categories of qualified persons authorized to prescribe, dispense, and administer COVID-19 vaccines authorized by the U.S. Food and Drug Administration…
>
> Under the PREP Act and the Declaration, a qualified person is a covered person. Subject to certain limitations, a covered person is **immune from suit and liability** under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure [*emphasis added*] if a declaration under the PREP Act has been issued with respect to such countermeasure."

[278] ***Public Readiness and Emergency Preparedness Act (PREPA)***
December 30, 2005
https://www.govinfo.gov/content/pkg/PLAW-109publ148/pdf/PLAW-109publ148.pdf

> "SEC. 319F–3. TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS AND SECURITY COUNTERMEASURES.
>
> (a) LIABILITY PROTECTIONS.—
>
> (1) IN GENERAL.—Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.
>
> (2) SCOPE OF CLAIMS FOR LOSS.—
>
> (A) LOSS.—For purposes of this section, the term 'loss' means any type of loss, including—
>
> (i) death;
>
> (ii) physical, mental, or emotional injury, illness, disability, or condition;
>
> (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and
>
> (iv) loss of or damage to property, including business interruption loss.
>
> Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.
>
> (B) SCOPE.—**The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure**, including a causal relationship with

the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure."

Note: "What Is a Countermeasure? A countermeasure is a vaccine, medication, device, or other item that is used to prevent, diagnose, or treat a public health emergency or a security threat."
https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicpfactsheet.pdf

[279] ***National Childhood Vaccine Injury Act of 1986 (H.R. 5546)***
October 14, 1986
https://www.congress.gov/bill/99th-congress/house-bill/5546

"**Title I: Vaccines - Subtitle 1: National Vaccine Program** - Amends the Public Health Service Act to establish in the Department of Health and Human Services a National Vaccine Program to: (1) direct vaccine research and development within the Federal Government; (2) ensure the production and procurement of safe and effective vaccines; (3) direct the distribution and use of vaccines; and (4) coordinate governmental and nongovernmental activities. Requires the Director of the Program to report to specified congressional committees…

Subtitle 2: National Vaccine Injury Compensation Program - Part A: Program Requirements - Establishes the National Vaccine Injury Compensation Program as an alternative remedy to judicial action for specified vaccine-related injuries…

Provides that compensation awarded under the Program shall be paid out of the National Vaccine Injury Compensation Trust Fund. Limits awards for actual and projected pain and suffering and emotional distress to $250,000. Prohibits awards for punitive damages…

Part B: Additional Remedies - Sets forth procedures under which the person who filed a petition for compensation under the program may elect to file a civil action for damages.

Provides that **no vaccine manufacturer shall be liable** in a civil action for damages arising from a vaccine-related injury or death: (1) **resulting from unavoidable side effects**; or (2) **solely due to the manufacturer's failure to provide direct warnings**. Provides that a manufacturer may be held liable where: (1) such manufacturer engaged in the fraudulent or intentional withholding of information; or (2) such manufacturer failed to exercise due care. Permits punitive damages in such civil actions under certain circumstances."

Past Violations and Fines

[280] **#Violation Tracker Parent Company Summaries**
Good Jobs First
As of April 4, 2023
https://www.goodjobsfirst.org/violation-tracker
About Us: "Violation Tracker UK is produced by Good Jobs First, a Washington, DC-based non-governmental organisation focused on corporate and government accountability. GJF's Corporate Research Project provides tools to assist campaigners, public officials, journalists, academics and others in analyzing the conduct of companies and industries. Among those tools is the original U.S. Violation Tracker, introduced in 2015 and expanded numerous times since then."

Pfizer: https://violationtracker.goodjobsfirst.org/parent/pfizer

Penalty total since 2000: $10,268,623,165

Number of records: 90

Healthcare-related offenses: 10 records for $3,373,675,000

Johnson & Johnson: https://violationtracker.goodjobsfirst.org/prog.php?parent=johnson-and-johnson

Penalty total since 2000: $15,008,224,699

Number of records: 74

Healthcare-related offenses: 15 records for $8,316,511,000

[281] **Corporate Rap Sheets**
Corporate Research Project
https://www.corp-research.org/home-page

Pfizer: https://www.corp-research.org/pfizer

Excerpt: "In the area of product safety, Pfizer's biggest scandal involved defective heart valves sold by its Shiley subsidiary that led to the deaths of more than 100 people. During the investigation of the matter, information came to light suggesting that the company had deliberately misled regulators about the hazards. Pfizer also inherited safety and other legal controversies through its big acquisitions, including a class action suit over Warner-Lambert's Rezulin diabetes medication, a big settlement over PCB dumping by Pharmacia, and thousands of lawsuits brought by users of Wyeth's diet drugs.

Also on Pfizer's list of scandals are a 2012 bribery settlement; massive tax avoidance; and lawsuits alleging that during a meningitis epidemic in Nigeria in the 1990s the company tested a risky new drug on children without consent from their parents."

See also '**Product Safety**' at link above.

Johnson & Johnson: https://www.corp-research.org/jnj

Excerpt: "Johnson & Johnson, which originally made its name in mundane products such as bandages and baby powder and shampoo, grew into a healthcare powerhouse by acquiring pharmaceutical and medical device businesses. Yet those purchases were largely responsible for the deterioration of a company once regarded as a model of social responsibility into a symbol of unreliability with a seemingly endless string of scandals involving tainted and deficient products. Those scandals have forced the company to pay out several billion dollars in civil settlements and criminal fines. It faces more penalties for its alleged role in the opioid crisis."

See also '**Product Safety and Contamination Issues**' at link above.

US Government Contracts with Vaccine Manufacturers

[282] **ADDED since 2/8/2022**
COVID-19 Contracts
Knowledge Ecology International
https://www.keionline.org/covid-contracts

"Below are links to copies of the contracts entered into by the US government for technologies to combat the COVID-19 pandemic. KEI is updating this page as we gain access to more contracts, and less redacted versions…

The list below contains COVID-19-related contracts obtained via Freedom of Information Act requests, Securities & Exchange Commission filings, and HHS reading room files. The bulk of KEI's database of contracts, however, was obtained via FOIA requests and lawsuits filed by KEI."

COVID-19 Vaccine Trials

Trial Durations and Completion Dates

[283] **Pfizer clinical trial**: ***Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study***
https://clinicaltrials.gov/ct2/show/NCT04848584

"Estimated Study Completion Date: **July 30, 2023**"

[284] **Moderna clinical trial:** ***A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19***
https://www.clinicaltrials.gov/ct2/show/NCT04470427

"Estimated Study Completion Date: **October 27, 2022**"

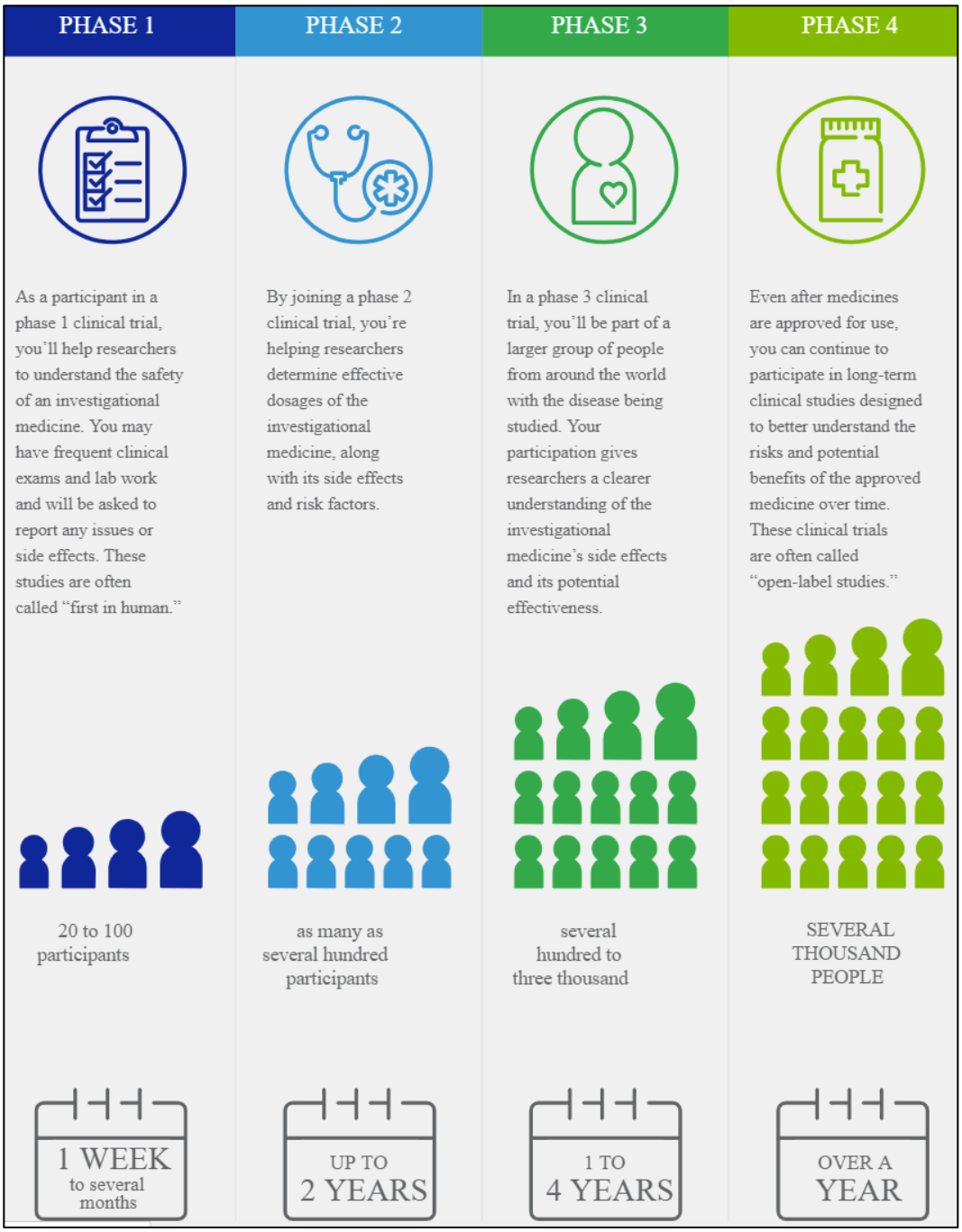
[285] **Johnson & Johnson clinical trial:** ***A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants***
https://clinicaltrials.gov/ct2/show/NCT04505722

"Estimated Study Completion Date: **January 2, 2023**"

[286] **Astrazeneca clinical trial:** ***Phase III Double-blind, Placebo-controlled Study of AZD1222 for the Prevention of COVID-19 in Adults***
https://web.archive.org/web/20201128213442/https://clinicaltrials.gov/ct2/show/results/NCT04516746

"Estimated Study Completion Date: **October 25, 2022**"

[287] ***The Four Phases of Clinical Trials***
Pfizer, Inc.
https://www.pfizer.com/science/clinical-trials/guide-to-clinical-trials/phases



Trial Endpoints

Note: Efficacy against SARS-CoV-2 transmission/infection and COVID-19 mortality were not endpoints (i.e., tested outcomes) stipulated by the Pfizer or Moderna trial papers.

[288] **Pfizer trial paper: *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine***
Pfizer, Inc.
Fernando P. Polack, Stephen J. Thomas, *et al*.
https://sci-hub.st/10.1056/NEJMoa2034577

> "The first primary end point was the efficacy of BNT162b2 against confirmed Covid-19 with onset at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose; the second primary end point was efficacy in participants with and participants without evidence of prior infection…
>
> Major secondary end points included the efficacy of BNT162b2 against severe Covid-19."

[289] **Moderna trial paper: *Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine***
Moderna, Inc.
Lindsey R. Baden, Hana M. El Sahly, *et al*.
https://www.nejm.org/doi/full/10.1056/NEJMoa2035389

> "The primary end point was the efficacy of the mRNA-1273 vaccine in preventing a first occurrence of symptomatic Covid-19 with onset at least 14 days after the second injection in the per-protocol population, among participants who were seronegative at baseline…
>
> A secondary end point was the efficacy of mRNA-1273 in the prevention of severe Covid-19… Additional secondary end points included the efficacy of the vaccine at preventing Covid-19 after a single dose or at preventing Covid-19 according to a secondary (CDC), less restrictive case definition…"

[290] ***Will covid-19 vaccines save lives? Current trials aren't designed to tell us***
British Medical Journal
Peter Doshi
October 21, 2020
https://www.bmj.com/content/371/bmj.m4037

> "**None of the trials** currently under way **are designed to detect a reduction in any serious outcome** such as hospital admissions, use of intensive care, or deaths. Nor are the vaccines being studied to determine whether they can interrupt transmission of the virus [*emphasis added*]…
>
> In all the ongoing phase III trials for which details have been released, laboratory confirmed infections even with only mild symptoms qualify as meeting the primary endpoint definition."

[291] **News release: *FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine***
US Food & Drug Administration
December 18, 2020
https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid

> "At this time, data are not available to determine how long the vaccine will provide protection, **nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person** [*emphasis added*]."

Trial Critiques, Whistleblowers, and Other Findings

Note: The citations below are presented in reverse, chronological order.

[292] **ADDED since 2/8/2022**
Sources of bias in observational studies of covid-19 vaccine effectiveness
Journal of Evaluation in Clinical Practice
Kasier Fung, Mark Jones, and Peter Doshi
March 26, 2023
https://onlinelibrary.wiley.com/doi/10.1111/jep.13839

> "**Introduction**: … In this article, we focus on three major sources of bias for which there is sufficient data to verify their existence, and show how they could substantially affect vaccine effectiveness estimates using observational study designs—particularly retrospective studies of large population samples using administrative data wherein researchers link vaccinations and cases to demographics and medical history….
>
> In each of our three illustrations, we compare results based on observational study methods against randomised controlled trial (RCT) methods. For each comparison, one side represents a published study while the other is a counterfactual. In each case, we show how the gap between observational and RCT study results is due to a source of bias…
>
> **Lessons Learned**: A recent commentary discussed multiple factors that can bias estimates of covid-19 vaccine effectiveness, such as vaccination status misclassification, testing differences, and disease risk factor confounding.7 Our article complements these observations by providing examples based on actual data sets that quantify how case-counting window bias, age bias, and background infection rate bias can profoundly complicate the analysis of observational studies, **shifting covid-19 vaccine effectiveness estimates by an absolute magnitude as high as 50% to 70%**...
>
> Our analysis shows that real-world conditions such as non-randomised vaccination, crossovers, and trends in background infection rates introduce strong, complex biases into these observational datasets. Our contribution is to size up three important biases, the magnitude of which surprised us and may surprise you. We conclude that "real-world" studies using methodologies popular in early 2021 overstate vaccine effectiveness. Our finding highlights how difficult it is to conduct high-quality observational studies during a pandemic."

[293] **ADDED since 2/8/2022**

BMF Investigation: *FDA oversight of clinical trials is "grossly inadequate," say experts*

British Medical Journal
Maryanne Demasi
November 16, 2022
https://www.bmj.com/content/379/bmj.o2628

> "Regulatory documents show that only nine out of 153 Pfizer trial sites were subject to FDA inspection before licensing the mRNA vaccine. Similarly, only 10 out of 99 Moderna trial sites and five of 73 remdesivir trial sites were inspected.
>
> Now, facing a backlog of site inspections, experts have criticised the FDA's oversight of clinical trials, describing it as 'grossly inadequate.' They say **the problem**, which predated covid-19, **is not limited to a lack of inspections but also includes failing to notify the public or scientific journals when violations are identified**—effectively keeping scientific misconduct from the medical establishment.
>
> The FDA is 'endangering public health' by not being candid about violations that are uncovered during clinical trial site inspections, says David Gortler, a pharmacist and pharmacologist who worked as an FDA medical reviewer between 2007 and 2011 and was then appointed as a senior adviser to the FDA commissioner in 2019-21…
>
> **Paused during the pandemic**
>
> Between March and July 2020, at the peak of pandemic restrictions, the FDA **paused its site inspections** and only 'mission critical' inspections were carried out. Gortler says, however, that this was the time that the FDA should have ramped up its oversight, not scaled back, especially since covid-19 products were being developed at warp speed and intended for millions of people…
>
> **Historical failure to oversee**
>
> The FDA has a **long history** of failing adequately to oversee clinical trial sites. A report in 2007 by the Department of Health and Human Services' Office of the Inspector General found the FDA audited less than 1% of the nation's clinical trial sites between 2000 and 2005 ..
>
> In 2015, Charles Seife, professor of journalism at New York University, conducted an analysis of published clinical trials between 1998 and 2013 in which an FDA inspection found significant evidence of objectionable practices. A total of 57 published clinical trials had significant evidence of one or more problems: **39%** had falsification or submission of false information, **25%** had problems with adverse events reporting, **74%** had protocol violations, **61%** had inadequate or inaccurate recordkeeping, and **53%** failed to protect the safety of patients or had problems with oversight or informed consent. Furthermore, only 4% of the trials that were found to have significant violations were mentioned in the study's journal publications."

[294] **ADDED since 2/8/2022**

Revealed: PR firm that represents Pfizer and Moderna also sits on CDC vaccine division - sparking major conflict of interest concerns

Daily Mail
Luke Andrews
October 12, 2022
https://www.dailymail.co.uk/health/article-11303017/PR-firm-represents-Pfizer-Moderna-sits-CDC-vaccine-advisory-committee.html

> "A PR company that represents Pfizer and Moderna has staff 'embedded' in the CDC's vaccine division, it has emerged.
>
> New York-based firm Weber Shandwick has been responsible for elevating Pfizer's profile since at least 2006. It partnered with Moderna in June this year, after the small biotech firm became a household name following its vaccine success.
>
> Yet questions are being raised about a possible conflict of interest as it emerged the company was hired by the Centers for Disease Control and Prevention (CDC) during the pandemic to boost its 'health communication'.
>
> It was involved in PR campaigns that encouraged Americans to get vaccinated against Covid."

[295] **ADDED since 2/8/2022**

Video: *Pfizer director admits vaccine was never tested on preventing transmission*

October 11, 2022
https://odysee.com/@Stefano:9/Rob-Roos-MEP-vs-Pfizer:a

> **Rob Roos (Holland), member of Europian Parliament (MEP)**: "In a COVID hearing in the European Parliament, one of the Pfizer directors just admitted to me, at the time of introduction, the vaccine had never been tested on stopping the transmission of the virus.
>
> This removes the entire legal basis for the COVID passport; the COVID passport that led to massive institutional discrimination as people lost access to essential parts of society. I find this to be shocking – even criminal…"
>
> **Exchange in EU hearing**
>
> **Roos**: "But to you, Ms. Small, I have the following short question, to which I would like to receive a clear response… Was the Pfizer COVID vaccine tested on stopping the transmission of the virus before it entered the market? If not, please say it clearly. If yes, are you willing to share the data with this committee? And I really want a straight answer, yes or now. I'm really looking forward to it."
>
> **Ms. Janine Small, President of International Developed Markets at Pfizer**: "Regarding the question around whether we knew about stopping immunization [*sic*] before it entered the market? No. These, you know, we had to really move at the speed of science to really understand what is taking place in the market."

[296] **ADDED since 2/8/2022**

Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults

Vaccine journal
Joseph Fraiman, Juan Erviti, *et al*.
August 31, 2022
https://www.sciencedirect.com/science/article/pii/S0264410X22010283

"**Abstract**

Introduction: In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials.

Methods: Secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427), focusing analysis on Brighton Collaboration adverse events of special interest.

Results: Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95 % CI −0.4 to 20.6 and −3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an excess risk of serious adverse events of special interest of 12.5 per 10,000 vaccinated (95 % CI 2.1 to 22.9); risk ratio 1.43 (95 % CI 1.07 to 1.92). The Pfizer trial exhibited a 36 % higher risk of serious adverse events in the vaccine group; risk difference 18.0 per 10,000 vaccinated (95 % CI 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of serious adverse events in the vaccine group: risk difference 7.1 per 10,000 (95 % CI –23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a **16 % higher risk of serious adverse events** in mRNA vaccine recipients: risk difference 13.2 (95 % CI −3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39).

Discussion: The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets."

[297] ***Covid-19 vaccines and treatments: we must have raw data, now***
British Medical Journal
Peter Doshi (senior editor), Fiona Godlee (former editor in chief), and Kamran Abbasi (editor in chief)
January 19, 2022
https://www.bmj.com/content/376/bmj.o102

> "Today, despite the global rollout of covid-19 vaccines and treatments, the anonymised participant level data underlying the trials for these new products remain inaccessible to doctors, researchers, and the public—and are likely to remain that way for years to come. This is morally indefensible for all trials, but especially for those involving major public health interventions…
>
> The lack of access to data is consistent across vaccine manufacturers…
>
> Pharmaceutical companies are reaping vast profits without adequate independent scrutiny of their scientific claims. The purpose of regulators is not to dance to the tune of rich global corporations and enrich them further; it is to protect the health of their populations. We need complete data transparency for all studies, we need it in the public interest, and we need it now."

[298] ***The Pfizer Inoculations For COVID-19 – More Harm Than Good***
Canadian Covid Care Alliance
December 2021
https://drive.google.com/file/d/1TW1rYf8eL8VfeBBDRJptZXQQU-1CRZI1/view
Video version (39m): https://rumble.com/vqx3kb-the-pfizer-inoculations-do-more-harm-than-good.html

> "**Who We Are**: Our alliance of over 500 independent Canadian doctors, scientists, and health care practitioners is committed to providing quality, balanced, evidence-based information to the Canadian public about COVID-19 so that hospitalizations can be reduced, lives saved, and our country safely restored to normal as quickly as possible…
>
> It's clear that Pfizer - and the agencies overseeing their trials - failed to follow established, high quality safety and efficacy protocols right from the beginning.
>
> We have presented **Level 1 evidence of harm from Pfizer's own trial data**. Any government which has approved these inoculations, much less mandated them, knew or should have known from the available data that harm would be caused to its citizens [*emphasis added*].
>
> Any government that approved this medical intervention for its citizens should have ensured that the trial had used the appropriate clinical endpoints and high quality safety science.
>
> Any government official who possesses this evidence and continues to allow its citizens to be inoculated with a toxic agent is, at the very least, negligent."

[299] ***Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial***
British Medical Journal
Paul D. Thacker
November 2, 2021
https://www.bmj.com/content/375/bmj.n2635

"Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise questions about data integrity and regulatory oversight…

A regional director who was employed at the research organisation Ventavia Research Group has told *The BMJ* that **the company falsified data, unblinded patients, employed inadequately trained vaccinators,** and **was slow to follow up on adverse events** reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding [*emphasis added*]. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided *The BMJ* with dozens of internal company documents, photos, audio recordings, and emails…

Poor laboratory management …

In a recording of a meeting in late September 2020 between Jackson and two directors a Ventavia executive can be heard explaining that the company wasn't able to quantify the types and number of errors they were finding when examining the trial paperwork for quality control. 'In my mind, it's something new every day,' a Ventavia executive says. 'We know that it's significant.' …

A history of lax oversight

When it comes to the FDA and clinical trials, Elizabeth Woeckner, president of Citizens for Responsible Care and Research Incorporated (CIRCARE), says the agency's oversight capacity is severely under-resourced. If the FDA receives a complaint about a clinical trial, she says the agency rarely has the staff available to show up and inspect. And sometimes oversight occurs too late…

'There's just a complete lack of oversight of contract research organisations and independent clinical research facilities,' says Jill Fisher, professor of social medicine at the University of North Carolina School of Medicine and author of *Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials*…

Other employee's accounts

In recent months Jackson has reconnected with several former Ventavia employees who all left or were fired from the company. One of them was one of the officials who had taken part in the late September meeting. In a text message sent in June the former official apologised, saying that 'everything that you complained about was spot on.'

Two former Ventavia employees spoke to *The BMJ* anonymously for fear of reprisal and loss of job prospects in the tightly knit research community. Both confirmed broad aspects of Jackson's complaint."

[300] **Video (6m): Statement by Peter Doshi**
US Congressional roundtable – Discussion on COVID-19 vaccines
Peter Doshi, Senior Editor at the British Medical Journal
November 2, 2021
https://www.bitchute.com/video/OvM5meOXk9o/

> "Clinical trials have shown that the vaccines authorized for use in the US are highly effective against COVID-19 infection, severe illness, and death."
> - Walensky, Walke, Fauci, February 2021
>
> **Doshi**: "'When that statement by prominent public health officials was penned, there had been just one death – one death – across the 70,000 Pfizer and Moderna trial participants. Today, we have more data and you can see that there were similar numbers of deaths in the vaccine and placebo groups [*15 and 14 deaths, respectively*]. The trials did not show a reduction in death. Even for COVID deaths, the evidence is flimsy, with just 2 deaths in the placebo group and one in the vaccine group…
>
> My point is that **those who claimed the trials showed the vaccines were highly effective in saving lives were wrong**. The trials did not demonstrate this [*emphasis added*]."

[301] **Video (5m): Statement by Dr. Robert Kaplan**
US Congressional roundtable – Discussion on COVID-19 vaccines
Dr. Robert Kaplan, Distinguished Research Professor Emeritus of Health Policy and Management (UCLA)
November 2, 2021
https://odysee.com/@walt3k:4/Roundtable-expert-panel-on-mandates-Johnson:4

> **Kaplan (starting at 1:07:45)**: "I do have concerns about research integrity and the process used to authorize, approve, and mandate vaccines during this emergency. Let me outline some of my concerns...
>
> (L)eading authorities have reported that the vaccines dramatically reduce deaths from COVID-19. Yet, inspection of the data from the Moderna and Pfizer clinical trials show that **death rates are identical** among those randomly assigned to the vaccines or to placebos [*emphasis added*]…
>
> My second concern is that serious scholars have not been able to examine the raw data that justify the FDA and CDC decisions. The evidence we have comes primarily from highly curated, industry-controlled press releases, and press releases do not provide the detail that we, as scientists, need to offer objective evaluations.
>
> More disturbing is that the **vaccine manufacturers are not honoring requests to provide raw data**. Pfizer, for example, will not make data publically available until 2025 [*emphasis added*]. This is really an unacceptable delay for a product that would be used by billions of people worldwide.
>
> Over the last 80 years, the FDA has evolved standards that require multiple studies and longer term follow-up.

My third concern is that the rapid development and deployment of vaccines to hundreds of millions of people required that some of the usual safeguards needed to be relaxed. Vaccines were authorized on the basis of a single trial with relatively short follow-up, in contrast to the typical standard of multiple trials with sufficient time to evaluate durability and harms…

In contrast to usual FDA applications, the vaccine studies have not made much of the information public. Among 72 studies on the Pfizer vaccine that are registered in ClinicalTrials.gov, **only one is shown to have been completed**, and **zero studies have reported their results publically** [*emphasis added*].

My final concern is that legitimate, scientific challenges have been set aside as 'misinformation'…

So what needs to be done? First, we need more transparency. We should insist on independent data analysis by investigators who are not employed by the vaccine manufacturers…

In summary, we are making big decisions on the basis of limited, highly selected evidence, a compromised scientific process may lead to poor decisions and it may set a bad precedent. So please remember that if it is in the public interest, in this case affecting hundreds of millions of people, it should be in the public domain."

[302] **Video (6m): Statement by Dr. Aditi Bhargava**
US Congressional roundtable – Discussion on COVID-19 vaccines
Dr. Aditi Bhargava, Professor with the Center for Reproductive Sciences and Dept. of Obstetrics and Gynecology (University of California, San Francisco)
November 2, 2021
https://odysee.com/@Anon:96/aditibhargava:f

Bhargava: "My name is Aditi Bhargava and I'm a professor at UCSF and a microbiologist with 33 years of research experience. These are my scientific views…

It should not have taken the Massachusetts breakthrough infections this summer to discover that fully vaccinated people are just as vulnerable to being infected and transmit SARS-CoV-2 as the unvaccinated. Had the trials been stringent, had the phase II and III [trials] stuck to the protocols of follow-up, had the regulators enforced manufacturers to study prevention of infection in their clinical trials, **this fiasco could have been avoided** [*emphasis added*].

Instead, manufacturers configured these trials to study the prevention of mild symptoms and used pre-clinical models, such as the rhesus monkeys, in whom the virus does not cause disease. If all we can do is prevent symptoms and severe disease [*then*] we should be talking about drugs to treat COVID, not vaccines and mandates.

We lost the opportunity of discovering these major shortcomings by torpedoing the clinical trials. **The placebo groups were eliminated just two months after the second dose**. Instead, we are learning through trial and error on hundreds of millions of people [*emphasis added*]. And, we insist on eliminating a very important control group by these vaccine mandates. There is no scientific study or experimental design in which we can learn anything of value without a control group. Certainly not about safety and efficacy.

Persistent high levels of antibodies often indicate […] to the body's immune system. That is the basis of autoimmune disease. Hence boosters' long-term adverse events should be taken seriously. The notion that we are in an emergency nearly two years after the pandemic [began] and that should justify cutting corners or taking short-cuts is simply wrong. Trust in scientific methods is at stake.

Media reports often state that [the] science is clear. But scientific publications do not think that the science is clear. And as you've heard from various testimonies – real people suffered adverse events and perhaps **life-long disabilities** due to sloppy trials [*emphasis added*].

I will conclude by asking you. If the vaccines don't prevent infection and transmission, surely mandating person A to protect person B is pointless? But if the vaccines are effective – in preventing infection and transmission [and] decreasing symptoms, hospitalisations rates and death – then what do the vaccinated fear?"

[303] ***Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months***
New England Journal of Medicine
S.J. Thomas, E.D. Moreira, Jr., *et al*.
September 15, 2021
https://www.nejm.org/doi/pdf/10.1056/NEJMoa2110345
Supplementary Appendix:
https://www.nejm.org/doi/suppl/10.1056/NEJMoa2110345/suppl_file/nejmoa2110345_appendix.pdf

"**Procedures**: The participants were randomly assigned in a 1:1 ratio to receive two 30-μg intramuscular injections, 21 days apart, of BNT162b2 (0.3 ml volume per dose) or saline placebo. Randomization was performed with an interactive Webbased system. Starting in December 2020, after BNT162b2 became available under emergency or conditional use authorizations, participants 16 years of age or older who became eligible for Covid-19 vaccination according to national or local recommendations were given the option to learn their trial assignment. Those who had been randomly assigned to receive placebo were offered BNT162b2. After **unblinding of the group assignments**, participants were followed in an open-label trial period [*emphasis added*]…

Adverse Events: … During the blinded, placebo-controlled period, 15 participants in the BNT162b2 group and 14 in the placebo group died; during the openlabel period, 3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died."

Notes*: Therefore, over the six-month period documented by this report, the treatment group had a total of 20 fatalities [15 + 5] while the placebo group had 14.*

According to Table S3 from the Supplementary Appendix *(link above, image below):*

- *Over the six-month period documented by this report,* ***the treatment group had 300% [(5,241 – 1,311) / 1,311] more "Related Adverse Events" (RAE)*** *than the placebo group. (An RAE is an event considered to be related to the injection by an investigator.)*
- *The treatment group also experienced 75% more "Severe Adverse Events" than the placebo group.*

Adverse Event	BNT162b2 (N[a]=21,926) n[b] (%)	Placebo (N[a]=21,921) n[b] (%)
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c,d]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period. The population included all ≥16-year-old participants who received ≥1 dose of vaccine irrespective of follow-up time. a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=Number of participants reporting ≥1 occurrence of the specified event category. For 'any event', n=number of participants reporting ≥1 occurrence of any event. c. Assessed by the investigator as related to investigational product. d. Shoulder injury related to vaccine administration, right axillary lymphadenopathy, and paroxysmal ventricular arrhythmia (as previously reported). Adverse events for 12–15-year-old participants were reported previously.[11]

[304] ***US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, "All Cause Severe Morbidity"***
Trends in Internal Medicine
J. Bart Classen
August 25, 2021
https://www.scivisionpub.com/pdfs/us-covid19-vaccines-proven-to-cause-more-harm-than-good-based-on-pivotal-clinical-trial-data-analyzed-using-the-proper-scientific--1811.pdf

"**Abstract**: Three COVID-19 vaccines in the US have been released for sale by the FDA under Emergency Use Authorization (EUA) based on a clinical trial design employing a surrogate primary endpoint for health, severe infections with COVID-19. This clinical trial design has been proven dangerously misleading. Many fields of medicine, oncology for example, have abandoned the use of disease specific endpoints for the primary endpoint of pivotal clinical trials (cancer deaths for example) and have adopted "all cause mortality or morbidity" as the proper scientific endpoint of a clinical trial. Pivotal clinical trial data from the 3 marketed COVID-19 vaccines was reanalyzed using 'all cause severe morbidity', a scientific measure of health, as the primary endpoint. 'All cause severe morbidity' in the treatment group and control group was calculated by adding all severe events reported in the clinical trials. Severe events included both severe infections with COVID-19 and all other severe adverse events in the treatment arm and control arm respectively. This analysis gives reduction in severe COVID-19 infections the same weight as adverse events of equivalent severity. Results prove that **none of the vaccines provide a health benefit** and **all pivotal trials show a statically significant increase in 'all cause severe morbidity'** in the vaccinated group compared to the placebo group [*emphasis added*]. The Moderna immunized group suffered 3,042 more severe events than the control group (p=0.00001). The Pfizer data

was grossly incomplete but data provided showed the vaccination group suffered 90 more severe events than the control group (p=0.000014), when only including 'unsolicited' adverse events. The Janssen immunized group suffered 264 more severe events than the control group (p=0.00001). These findings contrast the manufacturers' inappropriate surrogate endpoints: Janssen claims that their vaccine prevents 6 cases of severe COVD-19 requiring medical attention out of 19,630 immunized; Pfizer claims their vaccine prevents 8 cases of severe COVID-19 out of 21,720 immunized; Moderna claims its vaccine prevents 30 cases of severe COVID-19 out of 15,210 immunized. Based on this data it is all but a certainty that **mass COVID-19 immunization is hurting the health of the population** in general. Scientific principles dictate that the mass immunization with COVID-19 vaccines must be halted immediately because we face a looming vaccine induced public health catastrophe [*emphasis added*]."

[305] ***COVID-19 vaccine efficacy and effectiveness—the elephant (not) in the room***
Microbe (The Lancet)
Piero Olliaro, Els Torreele, and Michel Vaillant
April 20, 2021
https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext

"Although attention has focused on vaccine efficacy and comparing the reduction of the number of symptomatic cases, fully understanding the efficacy and effectiveness of vaccines is less straightforward than it might seem. Depending on how the effect size is expressed, a quite different picture might emerge.

Vaccine efficacy is generally reported as a relative risk reduction (RRR). It uses the relative risk (RR)—ie, the ratio of attack rates with and without a vaccine—which is expressed as 1–RR. Ranking by reported efficacy gives relative risk reductions of 95% for the Pfizer–BioNTech, 94% for the Moderna–NIH, 91% for the Gamaleya, 67% for the J&J, and 67% for the AstraZeneca–Oxford vaccines. However, RRR should be seen against the background risk of being infected and becoming ill with COVID-19, which varies between populations and over time. Although the RRR considers only participants who could benefit from the vaccine, the absolute risk reduction (ARR), which is the difference between attack rates with and without a vaccine, considers the whole population. **ARRs tend to be ignored because they give a much less impressive effect size than RRRs**: 1.3% for the AstraZeneca–Oxford, 1.2% for the Moderna–NIH, 1.2% for the J&J, 0.93% for the Gamaleya, and 0.84% for the Pfizer–BioNTech vaccines [*emphasis added*]."

[306] **ADDED since 2/8/2022**
Rapid Response: *Why don't Covid-19 vaccine trials report statistics for the first 14 days?*
British Medical Journal
Allan S. Cunningham, retired pediatrician
March 16, 2021
https://www.bmj.com/content/372/bmj.n728/rr-0

"Recently a pediatric colleague sent me this preprint link to a Danish cohort study of the Pfizer Covid-19 vaccine in long-term care facility residents and healthcare workers. (https://www.medrxiv.org/content/10.1101/2021.03.08.21252200v1.) It showed real-world effectiveness of two doses of the mRNA vaccine: 64% and 90% VE in the two groups respectively beyond seven days after the second dose.

However, from 0 to 14 days after the first dose the risk of Covid-19 infection was actually increased in vaccine recipients: in the LTCF residents VE was -40%, CI -62% to -2%; among healthcare workers VE was -104%, CI -118% to -91%.(Table 2).....By contrast, statistics for the 0 to 14 days after the first dose were not reported in the randomized trials of the Pfizer, Moderna, or AstraZeneca vaccines. (Polack et al, NEJM 2020;383:2603. Baden et al, NEJM 2021;384:403. Voysel et al, Lancet 2021;397:92) **Why not?** Are the manufacturers hiding negative data?"

[307] **ADDED since 2/8/2022**

COVID-19 Vaccine AstraZeneca (AZD1222): Clinical Overview on AZD1222 Anaphylaxis including Hypersensitivity

AstraZeneca

February 2021

https://icandecide.org/wp-content/uploads/2022/11/2022-10-24-IR0751D_Production_MHRA_000001-000166-166-pages.pdf#page=36

Note: This document was acquired with an information request submitted by the Informed Consent Action Network (ICAN) to the United Kingdom's FDA equivalent – the Medicines and Healthcare Products Registry Agency (MHRA) -- in April 2022. The request sought information relating to the MHRA's authorization of the AstraZeneca, Janssen, Moderna, and Pfizer COVID-19 vaccines.

"**5 Overview of Safety**…

5.1.3 Summary and Conclusion…

Anaphylaxis and Angioedema are reported in medical/scientific literature in association with other COVID-19 vaccines with a possible causal association.

Based on an assessment of available data, AstraZeneca has concluded that there is reasonable possibility of a **causal association** between AZD1222 and serious hypersensitivity including anaphylaxis/anaphylactic reaction. Therefore, the Core Data Sheet sections 4.4 and 4.8 will be amended to include information on anaphylaxis/anaphylactic reaction and angioedema as an adverse drug reaction associated with AZD1222…"

[308] ***Outcome Reporting Bias in COVID-19 mRNA Vaccine Clinical Trials***

Medicina (MDPI)

Ronald Brown, School of Public Health and Health Systems, University of Waterloo (Canada)

February 26, 2021

https://www.mdpi.com/1648-9144/57/3/199/htm

"**Abstract**: Relative risk reduction and absolute risk reduction measures in the evaluation of clinical trial data are **poorly understood by health professionals** and the public. The absence of reported absolute risk reduction in COVID-19 vaccine clinical trials can lead to outcome reporting bias that affects the interpretation of vaccine efficacy. The present article uses clinical epidemiologic tools to critically appraise reports of efficacy in Pfzier/BioNTech and Moderna COVID-19 mRNA vaccine clinical trials. Based on data reported by the manufacturer for Pfzier/BioNTech vaccine BNT162b2, this critical appraisal shows: relative risk reduction, 95.1%; 95% CI, 90.0% to 97.6%; p = 0.016; absolute risk reduction, 0.7%; 95% CI, 0.59% to 0.83%; p < 0.000. For the Moderna vaccine mRNA-1273, the appraisal shows: relative risk reduction, 94.1%; 95% CI, 89.1% to 96.8%; p = 0.004; absolute risk reduction,

1.1%; 95% CI, 0.97% to 1.32%; p < 0.000. **Unreported absolute risk reduction measures of 0.7% and 1.1% for the Pfzier/BioNTech and Moderna vaccines**, respectively, are very much lower than the reported relative risk reduction measures. **Reporting absolute risk reduction measures is essential to prevent outcome reporting bias in evaluation of COVID-19 vaccine efficacy** [*emphasis added*]."

[309] **ADDED since 2/8/2022**

2.5 Clinical Overview: AZD1222 Marketing Authorisation Application - Primary Analysis (Data Cut-off 07 December 2020)

AstraZeneca

February 25, 2021

http://paracom.paramountcommunication.com/ct/61337132:saDMIlDkN:m:1:2369845015:852D3E268A8A26E2711D4191B67B6A23:r

Note: This document was acquired with FOIA request submitted by the Informed Consent Action Network (ICAN) to the United Kingdom's FDA equivalent – the Medicines and Healthcare Products Registry Agency (MHRA) -- in April 2022. The request sought information relating to the MHRA's authorization of the AstraZeneca, Janssen, Moderna, and Pfizer COVID-19 vaccines.

"**6.2 Risks of AZD1222**

The updated evaluation of the safety of AZD1222 is based on the pooled population from 4 **ongoing studies**, comprising 24244 male and female adults aged from [REDACTED] years to [REDACTED] years…

Long-term follow-up of the ongoing clinical studies (up to 1 year) will provide data to further characterise the safety profile of AZD1222. Moreover, since people with severe immunodeficiencies, severe underlying comorbid disease, and pregnant/lactating women were excluded from the studies, the safety of AZD1222 in these groups is **currently unknown**."

[310] **ADDED since 2/8/2020**

Interim position paper: considerations regarding proof of COVID-19 vaccination for international travelers

World Health Organization

February 5, 2021

https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers

"**Introduction**: The World Health Organization (WHO) issues regularly updated position papers on vaccines against diseases that have an international public health impact. This paper, which presents WHO's position on the advisability of requirements for COVID-19 vaccination or proof of vaccination for international travellers, is designed for use mainly by national public health officials and managers of immunization programmes…

WHO position: At the present time, it is WHO's position that national authorities and conveyance operators should not introduce requirements of proof of COVID-19 vaccination for international travel as a condition for departure or entry, given that there are still critical unknowns regarding the efficacy of vaccination in reducing transmission…

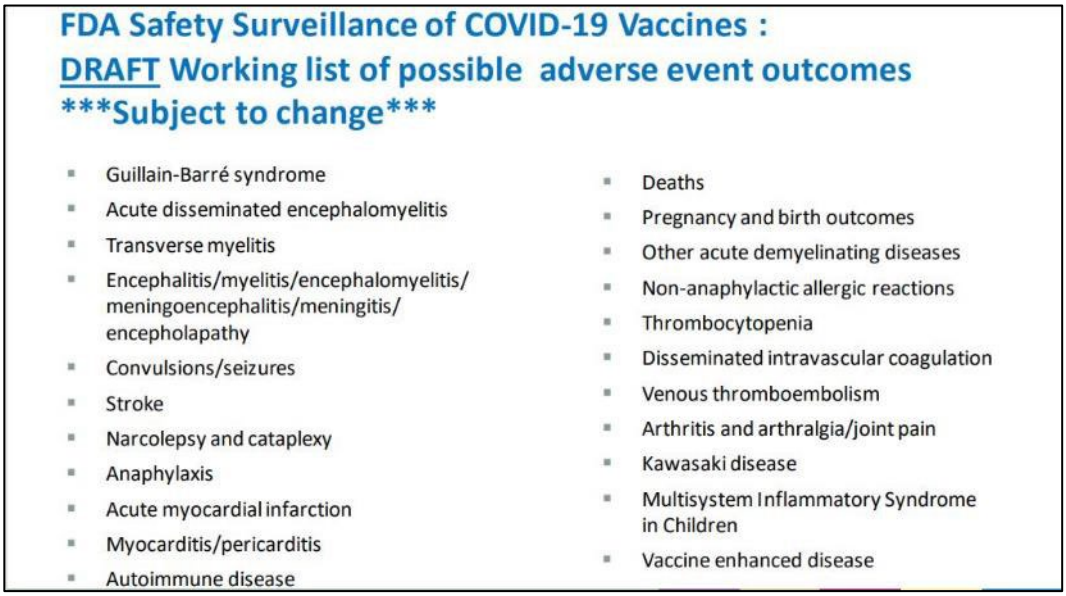
Scientific considerations: A number of scientific unknowns remain concerning the effectiveness of COVID-19 vaccines: **efficacy in preventing disease and limiting transmission**, including for variants of SARS-CoV-2; duration of protection offered by vaccination; timing of booster doses; whether vaccination offers protection against asymptomatic infection; age and population groups that should be prioritized for vaccination, specific contraindications, how long before travel vaccines should be offered; and possible exemption of people who have antibodies against SARS-CoV-2."

[311] **ADDED since 2/8/2020**

CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectivenes

Vaccines and Related Biological Products Advisory Committee Meeting Presentation
October 22, 2020
https://www.fda.gov/media/143557/download

This slide is evidence the FDA was aware of the possibility COVID-19 vaccines might incur the listed adverse events in October of 2020.



Administration of COVID-19 Vaccines

Emergency Use Authorizations (EUA)

Note: The citations below are presented in reverse, chronological order.

[312] **ADDED since 2/8/2022**
#Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) — Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)
Janssen Pharmaceutical Companies
Revised May 5, 2022
https://www.fda.gov/media/146304/download

"INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the 'Vaccine Information Fact Sheet for Recipients and Caregivers' (and provide a copy or direct the individual to the website www.janssencovid19vaccine.com to obtain the Fact Sheet) prior to the individual receiving the Janssen COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an FDA-approved vaccine.
- There is an option to accept or refuse the Janssen COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Janssen COVID-19 Vaccine, and the extent to which such risks and benefits are **unknown** [sic]…

[313] ***Summary Basis for Regulatory Action***
Food and Drug Administration (FDA)
From: Ramachandra Naik, PhD, Review Committee Chair, DVRPA/OVRR
Applicant: BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)
November 8, 2021
https://www.fda.gov/media/151733/download

"In the U.S., there are no licensed vaccines or anti-viral drugs for the prevention of COVID-19…

7. Safety and Pharmacovigilance…

Among participants 16 through 55 years of age who had received at least 1 dose of COMIRNATY (N=12,995) or placebo (N=13,026), serious adverse events from Dose 1 up to the participant unblinding date in ongoing follow-up were reported by 103 (0.8%) COMIRNATY recipients and 117 (0.9%) placebo recipients. In a similar analysis in participants 56 years of age and older (COMIRNATY=8,931, placebo=8,895), serious adverse events were reported by 165 (1.8%) COMIRNATY recipients and 151 (1.7%) placebo recipients who received at least 1 dose of COMIRNATY or placebo, respectively...

From Dose 1 through the March 13, 2021 data cutoff date, there were a total of 38 deaths, 21 in the COMIRNATY group and 17 in the placebo group. None of the deaths were considered related to vaccination."

[314] ***Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus***
Food and Drug Administration (FDA)
Revised August 12, 2021
https://www.cvlga.org/wp-content/uploads/EUA-27034_FS-for-Recipients-and-Caregivers_myocarditis-pericarditis_Final_6.25.2021-1.pdf

"The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19…

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)? The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA… The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives."

[315] ***FDA Briefing Document - Moderna COVID-19 Vaccine***
Food and Drug Administration (FDA)
December 17, 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_2b26a980a8d44de89cd21c42af406565.pdf

"**1. Executive Summary**: …).). The proposed use under an EUA is for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older …

2.3. U.S. Requirements to Support Issuance of an EUA for a Biological Product: … In the event an EUA is issued for this product, it would still be considered unapproved and it would be under further investigation…

2.6 Safety and Effectiveness Information Needed to Support an EUA

Effectiveness data: Issuance of an EUA requires a determination that the known and potential benefits of the vaccine outweigh the known and potential risks. For a preventive COVID-19 vaccine to be potentially administered to millions of individuals, including healthy individuals, data adequate to inform an assessment of the vaccine's benefits and risks and support issuance of an EUA would include **meeting the prespecified success criteria for the study's primary efficacy endpoint** [*emphasis added*].

5.2 Study mRNA-1273-P301

5.2.1 Design …

Primary Efficacy Endpoint: The primary efficacy endpoint was efficacy of the vaccine to prevent protocol-defined COVID-19 occurring at least 14 days after the second dose in

participants with negative SARS-CoV-2 status at baseline…

5.2.6 Safety: … The safety analyses presented in this review are largely derived from the November 11, 2020 dataset that was the basis for the November 30, 2020 EUA request. **FDA has not independently verified the complete safety dataset and analyses** from the cutoff date of November 25, 2020 [*emphasis added*].

Pregnancies: Study participants of childbearing potential were screened for pregnancy prior to each vaccination, with a positive test resulting in exclusion or discontinuation from study vaccination… Pregnancy outcomes are otherwise unknown at this time.

6. Sponsor's Plans for Continuing Blinded, Placebo-Controlled Follow-Up: … ModernaTX is evaluating the opportunity to amend the protocol to proactively reconsent participants who received placebo to be offered mRNA-1273 vaccination and to remain in the trial, enabling ModernaTX to continue to collect the relevant safety and effectiveness data over the entire two years of follow-up while increasing the likelihood of retaining participants on trial. [***Question:*** *Administering the Moderna product to the placebo group would corrupt the study. How many participants in this group have now been inoculated?*]

8. Benefit/Risk Assessment in the Context of Proposed Indication and Use Under EUA

8.2 Unknown Benefits/Data Gaps

Duration of Protection: As the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months…

Effectiveness in certain populations at high-risk of severe COVID-19: Although the proportion of participants at high risk of severe COVID-19 is adequate for the overall evaluation of safety in the available follow-up period, the subsets of certain groups such as immunocompromised individuals (e.g., those with HIV/AIDS) are too small to evaluate efficacy outcomes.

Effectiveness in individuals previously infected with SARS-CoV-2: … [T]he study was not designed to assess the benefit in individuals with prior SARS-CoV-2 infection.

Vaccine effectiveness against mortality: A larger number of individuals at high risk of COVID-19 and higher attack rates **would be needed to confirm efficacy** of the vaccine against mortality [*emphasis added*].

Vaccine effectiveness against transmission of SARS-CoV-2: Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination… Additional evaluations including data from clinical trials and from vaccine use post-authorization **will be needed to assess the effect** of the vaccine in preventing virus shedding and transmission [*emphasis added*], in particular in individuals with asymptomatic infection.

8.4 Unknown Risks/Data Gaps

Safety in certain subpopulations: There are **currently insufficient data to make conclusions about the safety of the vaccine** in subpopulations such as children less than 16 years of age, pregnant and lactating individuals, and immunocompromised individuals [*emphasis added*].

10. Appendix A. Phase 1 and 2 Studies

Study Design: Study mRNA-1273-P201 is an ongoing phase 2a, randomized, observer-blind, placebo-controlled, dose-confirmation study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1273 in healthy adults 18 years and older."

[316] ***FDA Briefing Document - Pfizer-BioNTech COVID-19 Vaccine***
Food and Drug Administration (FDA)
December 10, 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_1136b2851e6e48b1886457ab98b4feef.pdf

"**1. Executive Summary**: … The proposed use under an EUA is 'for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.' …

2.3. U.S. Requirements to Support Issuance of an EUA for a Biological Product: … In the event an EUA is issued for this product, it would still be considered unapproved and it would be under further investigation…

Pregnancies: Female study participants of childbearing potential were screened for pregnancy prior to each vaccination, with a positive test resulting in exclusion or discontinuation from study vaccination… Pregnancy outcomes are otherwise unknown at this time.

Duration of Protection: As the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months…

Vaccine effectiveness against mortality: A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality.

Vaccine effectiveness against transmission of SARS-CoV-2: Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination… Additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection.

Safety in certain subpopulations: There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 16 years of age, pregnant and lactating individuals, and immunocompromised individuals.

Vaccine-enhanced disease. Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure."

[317] ***Emergency Use Authorization for Vaccines to Prevent COVID-19 - Guidance for Industry***
Food and Drug Administration (FDA)
October 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_c7b1f58e161f41f3833918dc5d4091ba.pdf

"III. Criteria and Considerations for the Issuance of an EUA for a COVID-19 Vaccine… Based on this declaration and determination, FDA may issue an EUA after FDA has determined that the following statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)) (Ref. 3): …

- **There is no adequate, approved, and available alternative** to the product for diagnosing, preventing, or treating the disease or condition [*emphasis added*]."

FDA Approval of Pfizer-BioNTech COVID-19 BNT162b2 Vaccine

Note: The citations below are presented in reverse, chronological order.

[318] ***Comirnaty (COVID-19 mRNA Vaccine) Risk Management Plan***
Pfizer, Inc.
November 25, 2021
https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf

"**SVII.1.2. Risks Considered Important for Inclusion in the List of Safety Concerns in the RMP**

Important Identified Risk: Anaphylaxis…

Important Identified Risk: Myocarditis and Pericarditis…

Important Potential Risk: Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)…

Missing Information: Use in Pregnancy and while breast feeding…

Missing Information: Use in immunocompromised patients…

Missing Information: Use in frail patients with co-morbidities (e.g. chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders)…

Missing Information: Use in patients with autoimmune or inflammatory disorders…

Missing Information: Interaction with other vaccines…

Missing Information: Long term safety data… The long-term safety of COVID-19 mRNA vaccine is unknown at present…

Table 52. Use in Pregnancy and while Breast Feeding…

The safety profile of the vaccine is **not known** in pregnant or breastfeeding women [*emphasis added*] due to their initial exclusion from the pivotal clinical study. There may be pregnant women who choose to be vaccinated despite the lack of safety data. It will be important to follow these women for pregnancy and birth outcomes. The timing of vaccination in a pregnant woman and the subsequent immune response may have varying favourable or unfavourable impacts on the embryo/foetus.

Table 53. Use in Immunocompromised Patients…

The vaccine has **not been studied** in individuals with overt immunocompromised conditions [*emphasis added*]. Therefore, further safety data will be sought in this population…

Table 54. Use in Frail Patients with Co-morbidities (e.g., chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders)…

The vaccine has been studied in individuals with stable chronic diseases (e.g., hypertension, obesity), however it has **not been studied** in frail individuals with severe co-morbidities that may compromise immune function due to the condition or treatment of the condition [*emphasis added*]. Therefore, further safety data will be sought in this population…

Safety data will be collected in individuals who are frail due to age or debilitating disease in the active surveillance studies and through routine pharmacovigilance.

Table 55. Use in Patients with Autoimmune or Inflammatory Disorders…

There is **limited information** on the safety of the vaccine in patients with autoimmune or inflammatory disorders [*emphasis added*]…

Table 56. Interaction with other Vaccines…

There are **no data** on interaction of COVID-19 mRNA vaccine with other vaccines [*emphasis added*] at this time…

Table 57. Long Term Safety Data …

At this time, 2-month post dose 2 safety data are available for approximately half of the patients who have received COVID-19 mRNA vaccine in Study C4591001. The study is ongoing…

At the time of vaccine availability, the long-term safety of COVID-19 mRNA vaccine is **not fully known** [*emphasis added*]."

[319] ***Does the FDA think these data justify the first full approval of a covid-19 vaccine?***
British Medical Journal
Peter Doshi
August 23, 2021
https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/

> "Approval imminent without data transparency, or even an advisory committee meeting?
>
> Last December, with limited data, the FDA granted Pfizer's vaccine an EUA, enabling access to all Americans who wanted one. It sent a clear message that the FDA could both address the enormous demand for vaccines without compromising on the science. A 'full approval' could remain a high bar.
>
> But here we are, with FDA reportedly on the verge of granting a marketing license 13 months into the still ongoing, two year pivotal trial, with **no reported data past 13 March 2021, unclear efficacy after six months due to unblinding, evidence of waning protection irrespective of the Delta variant,** and **limited reporting of safety data** [*emphasis added*]…
>
> Prior to the preprint, my view, along with a group of around 30 clinicians, scientists, and patient advocates, was that there were simply too many open questions about all covid-19 vaccines to support approving any this year. The preprint has, unfortunately, addressed very few of those open questions, and has raised some new ones.
>
> I reiterate our call: 'slow down and get the science right—there is no legitimate reason to hurry to grant a license to a coronavirus vaccine.'
>
> FDA should be demanding that the companies complete the two year follow-up, as originally planned (even without a placebo group, much can still be learned about safety). They should demand adequate, controlled studies using patient outcomes in the now substantial population of people who have recovered from covid. And regulators should bolster public trust by helping ensure that everyone can access the underlying data."

[320] **Approval letter: *Biologics License Application (BLA) Approval for BioNTech (Pfizer) Manufacturing GmbH***
US Food & Drug Administration
Mary A. Malarkey and Marion F. Gruber
August 23, 2021
https://www.fda.gov/media/151710/download

> "**Pediatric Requirements**: … We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed…

Label your annual report as an 'Annual Status Report of Postmarketing Study Requirement/Commitments' and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.
Final Protocol Submission: October 7, 2020
Study Completion: **May 31, 2023**
Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.
Final Protocol Submission: February 8, 2021
Study Completion: **November 30, 2023**
Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.
Final Protocol Submission: January 31, 2022
Study Completion: **July 31, 2024**
Final Report Submission: October 31, 2024…

Postmarketing Commitments to Reporting Requirements under Section 506B: We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled 'Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.'
Final Protocol Submission: July 1, 2021
Study Completion: **June 30, 2025**
Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.
Final Protocol Submission: September 30, 2021
Study Completion: **November 30, 2023**
Final Report Submission: May 31, 2024"

[321] **News release: *FDA Approves First COVID-19 Vaccine***
Food and Drug Administration
August 23, 2021
https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

"**Ongoing Safety Monitoring**: The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct postmarketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty. These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination with Comirnaty. In addition, although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty during pregnancy."

COVID-19 Vaccine Composition and Dynamics

mRNA Technology

[322] ***mRNA Platform: Enabling Drug Discovery & Development***
Moderna, Inc.
https://www.modernatx.com/mrna-technology/mrna-platform-enabling-drug-discovery-development

"**Our Operating System**

Recognizing the broad potential of mRNA science, we set out to create an mRNA technology platform that functions very much like an operating system on a computer. It is designed so that it can plug and play interchangeably with different programs. In our case, the 'program' or 'app' is our mRNA drug - the unique mRNA sequence that codes for a protein…

Our mRNA Medicines – The 'Software of Life'

When we have a concept for a new mRNA medicine and begin research, fundamental components are already in place.

Generally, the only thing that changes from one potential mRNA medicine to another is the coding region – the actual genetic code that instructs ribosomes to make protein. Utilizing these instruction sets gives our investigational mRNA medicines a software-like quality. We also have the ability to combine different mRNA sequences encoding for different proteins in a single mRNA investigational medicine.

We are leveraging the flexibility afforded by our platform and the fundamental role mRNA plays in protein synthesis to pursue mRNA medicines for a broad spectrum of diseases."

[323] **ADDED since 2/8/2022**

Form S-1 Registration Statement Under the Securities Act of 1933: BioNTech SE
United States Securities and Exchange Commission
September 9, 2019
https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330df1.htm

See also [275].

"**Risks related to our business**…

To our knowledge, there is **no current precedent** for an mRNA-based immunotherapy such as the type we are developing being approved for sale by the FDA, European Commission or any other regulatory agency elsewhere in the world. Although we expect to submit BLAs [*Biologics License Application*s] for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as **gene therapy medicinal products**, other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications... Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use."

[324] **ADDED since 2/8/2022**

Form S-1 Registration Statement Under the Securities Act of 1933: Moderna, Inc.
United States Securities and Exchange Commission
November 9, 2018
https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473ds1.htm

See also [275].

"**Risks related to our business and creating a new category of medicines**…

No mRNA drug has been approved in this new potential category of medicines, and may never be approved as a result of efforts by others or us. mRNA drug development has **substantial clinical development** and regulatory **risks** due to the novel and unprecedented nature of this new category of medicines…

Currently, mRNA is considered a **gene therapy product** by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and could act as a source of side effects, mRNA based medicines are designed to not irreversibly change cell DNA; however, side effects observed in gene therapy could negatively impact the perception of mRNA medicines despite the differences in mechanism. In addition, because no product in which mRNA is the primary active ingredient has been approved, the regulatory pathway for approval is uncertain. The number and design of the clinical and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for gene therapy products or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one pharmaceutical product to the next, and may be difficult to predict."

[325] **ADDED since 2/8/2022**

Gene vaccines

Annals of Internal Medicine
Indresh K. Srivastava and Margaret A. Liu
April 1, 2003
https://www.acpjournals.org/doi/10.7326/0003-4819-138-7-200304010-00011

> "Gene vaccines are a new approach to immunization and immunotherapy in which, rather than a live or inactivated organism (or a subunit thereof), one or more genes that encode proteins of the pathogen are delivered."

[326] **ADDED since 2/8/2022**

Long Term Follow-Up After Administration of Human Gene Therapy Products Guidance for Industry

US Department of Health and Human Services
January 2020
https://www.fda.gov/media/113768/download

> "**III. Background**
>
> A**. Potential Risks of Delayed Adverse Events Following Exposure to Human Gene Therapy Products**…
>
> Characteristics unique to human GT [*gene therapy*] products that may be associated with delayed adverse events include: …
>
> **3. Prolonged expression**: A GT product where the transgene (therapeutic gene) encodes growth factors, such as vascular endothelial growth factor (VEGF) or proteins associated with cell division such as p53, may raise the potential for unregulated cell growth and malignancies due to prolonged exposure to the therapeutic protein. Similarly, transgenes encoding immune recognition factors may introduce the risk for autoimmune-like reactions (to self-antigens) upon prolonged exposure. For GT products that carry transcriptional regulatory elements (e.g., microRNA) or immune-modulatory proteins (e.g., cytokines) there is also the **risk of unknown pleotropic effects**, including altered expression of host (human) genes that could result in unpredictable and undesirable outcomes.
>
> **4. Latency**: When the GT product has the potential for latency, such as a herpesvirus, there is the potential for reactivation from latency and the risk of delayed adverse events related to a symptomatic infection.
>
> **5. Establishment of persistent infections**: GT products that are replication competent viruses and bacteria, such as listeria-based bacterial vectors, have the potential to establish persistent infections in immunocompromised patients leading to the risk of developing a delayed but serious infection."

Reverse Transcription

Note: The citations below are presented in reverse, chronological order.

[327] **ADDED since 2/8/2022**
Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line
Current Issues in Molecular Biology — Lund University, Sweden
Markus Aldén, Francisko Olofsson Falla, *et al*.
February 25, 2022
https://www.mdpi.com/1467-3045/44/3/73

"**Abstract**: Preclinical studies of COVID-19 mRNA vaccine BNT162b2, developed by Pfizer and BioNTech, showed reversible hepatic effects in animals that received the BNT162b2 injection. Furthermore, a recent study showed that **SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of human cells**. In this study, we investigated the effect of BNT162b2 on the human liver cell line Huh7 in vitro. Huh7 cells were exposed to BNT162b2, and quantitative PCR was performed on RNA extracted from the cells. We detected high levels of BNT162b2 in Huh7 cells and changes in gene expression of long interspersed nuclear element-1 (LINE-1), which is an endogenous reverse transcriptase. Immunohistochemistry using antibody binding to LINE-1 open reading frame-1 RNA-binding protein (ORFp1) on Huh7 cells treated with BNT162b2 indicated increased nucleus distribution of LINE-1. PCR on genomic DNA of Huh7 cells exposed to BNT162b2 amplified the DNA sequence unique to BNT162b2. Our results indicate a fast up-take of BNT162b2 into human liver cell line Huh7, leading to changes in LINE-1 expression and distribution. We also show that **BNT162b2 mRNA is reverse transcribed intracellularly into DNA in as fast as 6 h upon BNT162b2 exposure**…

Discussion: … Our study shows that **BNT162b2 can be reverse transcribed to DNA** in liver cell line Huh7, and this may give rise to the concern if BNT162b2-derived **DNA may be integrated into the host genome and affect the integrity of genomic DNA, which may potentially mediate genotoxic side effects**. At this stage, we do not know if DNA reverse transcribed from BNT162b2 is integrated into the cell genome. Further studies are needed to demonstrate the effect of BNT162b2 on genomic integrity, including whole genome sequencing of cells exposed to BNT162b2, as well as tissues from human subjects who received BNT162b2 vaccination…

Conclusions: Our study is the first in vitro study on the effect of COVID-19 mRNA vaccine BNT162b2 on human liver cell line. We present evidence on fast entry of BNT162b2 into the cells and subsequent intracellular reverse transcription of BNT162b2 mRNA into DNA."

[328] ***Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues***
Proceedings of the National Academy of Sciences
Liguo Zhang, Alexsia Richards, *et al*.
May 25, 2021
https://www.pnas.org/content/118/21/e2105968118
Response by Rhys Parry, *et al.*, August 3, 2021:
https://www.pnas.org/content/118/33/e2109066118
Response to Parry, *et al.*, by Zhang, Richards, *et al.*, August 17, 2021
https://www.pnas.org/content/118/33/e2109497118

> "**Significance**: An unresolved issue of SARS-CoV-2 disease is that patients often remain positive for viral RNA as detected by PCR many weeks after the initial infection in the absence of evidence for viral replication. We show here that **SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of the infected cell** and be expressed as chimeric transcripts fusing viral with cellular sequences [*emphasis added*]. Importantly, such chimeric transcripts are detected in patient-derived tissues. Our data suggest that, in some patient tissues, the majority of all viral transcripts are derived from integrated sequences. Our data provide an insight into the consequence of SARS-CoV-2 infections that may help to explain why patients can continue to produce viral RNA after recovery."

[329] ***SARS-CoV-2 RNA reverse-transcribed and integrated into the human genome***
Whitehead Institute for Biomedical Research (Cambridge, MA)
Liguo Zhang, Alexsia Richards, *et al*., December 13, 2020
https://www.biorxiv.org/content/10.1101/2020.12.12.422516v1.full

> "**Summary**: … [W]e describe evidence that SARS-CoV-2 RNAs can be reverse transcribed in human cells by reverse transcriptase (RT) from LINE-1 elements or by HIV-1 RT, and that these DNA sequences can be integrated into the cell genome and subsequently be transcribed. Human endogenous LINE-1 expression was induced upon SARS-CoV-2 infection or by cytokine exposure in cultured cells, suggesting a molecular mechanism for SARS-CoV-2 retro-integration in patients. This novel feature of SARS-CoV-2 infection may explain why patients can continue to produce viral RNA after recovery and suggests a new aspect of RNA virus replication."

[330] ***How Bad is My Batch? Batch codes and associated deaths, disabilities and illnesses for Covid 19 Vaccines***
Craig Paardekooper, Michael Yeadon, Alexandra Latypova, Craig Paardekooper, Jessica Rose, and Walter Wagner
https://howbad.info/

> "Some batches/lots are associated with excessive deaths. This variation could be due to -
>
> - variation in the amount, meaning the number of doses distributed for a particular lot, OR
> - variation in the toxicity of the doses
>
> Both factors may play a part. Until we know for certain, it is best to be cautious.
>
> You can use this website to **find out the number of deaths, disabilities and illnesses associated with your particular batch code** [*emphasis added*]. The sheer number of deaths and disabilities is cause for concern - far exceeding the adverse events associated with flu vaccine lots of equal size."

Note: The citations below are presented in reverse, chronological order.

[331] **ADDED since 2/8/2022**
An Independent Analysis of the Manufacturing and Quality Issues of the BNT162b BioNTech/Pfizer Quasi-vaccine based on the European Medicines Agency's Public Assessment Report (EPAR)
Canadian Covid Care Alliance
Maria Gutschi, David J. Speicher, *et al*.
October 29, 2022
https://www.canadiancovidcarealliance.org/wp-content/uploads/2022/11/22OC29_EMA-Analysis-of-BNT162b-Manufacture.pdf

> "This article summarizes the main findings of a more detailed technical assessment concerning the development and manufacturing of the BioNTech/Pfizer's COVID-19 quasi-vaccine BNT162b. A number of deficiencies in the product's development were identified by regulatory agencies and appear to have either been ignored or glossed over. Vaccine approval for the declared COVID-19 pandemic was given 'fast-track 'conditional approval to address 'a seriously debilitating, rare or life-threatening disease devoid of a viable treatment' and approval was granted on the condition that additional information would be forthcoming after the vaccine was rolled out. This data has not been fully provided to date.
>
> Data for this review was primarily obtained from the European Medicines Agency European Public Assessment Report (EPAR) for the BioNTech/Pfizer vaccine. Additional information was obtained through email leaks from December, 2020 that were released to journalists and to the British Medical Journal…

The quasi-vaccine quality is questionable and variable. There may be **substantial differences in the mRNA vaccines between batches** and even between vials. This may be due to variations in handling, freezing/thawing/dilution requirements, the short half-life of the mRNA, and manufacturing variability…

It appears that there is insufficient evidence that this vaccine product meets the quality required of a pharmaceutical product, raising concerns about its safety and efficacy… Real-world data falsifies the original claim that mRNA based COVID-19 biologics function as an authentic vaccine for preventing viral infection and transmission rather than as a short-term gene-based therapeutic agent that might alleviate at best symptom severity. With this in mind, the **authorization for these products should be suspended** until the concerns in this review have been resolved and publicly verified by the regulatory authorities."

[332] ***Panel of doctors in Nashville, Tennessee***
Participants included Larry Pavlevsky MD, Robert Reinders MD, Alwin Moss MD, and James Neueschwander MD
Professional bios: https://www.beaufortcountynow.com/post/51354
January 2022
https://rumble.com/vt5fx0-what-is-in-the-mrna-vaccines.html

"**Questioner**: So all that sets up this question… what is really in these things because I just don't have access to a microscope to go look at it…

Pavlevsky: So because these injections are experimental, and they're only being used under the EUA, **we do not know the full list of ingredients that's in them**. No one knows. We do know that there's supposed to be messenger RNA to manufacture spike protein. We found out that there's also messenger RNA in there to stop the body from stopping the body from removing the messenger RNA. We know that there's lipid nanoparticles in there. We know that there's polyethylene glycol in there. What else is in there? **We don't know**. And no one is holding them responsible for letting us know what is in the shots [*emphasis added*]…

Neueschwander: Let's just start with the phospholipids that are in there. All right. So these are completely unnatural phospholipids, they do not occur in nature, they are manmade, they have the opposite polarity of any other phospholipid. Why does that matter? Because every membrane in your body is made of phospholipids. So what happens when you take a phospholipid that has the opposite charge? It's going to bind to those membranes. What happens when that occurs? **We don't know**. Why? Because they never did animal studies [*emphasis added*]. This is the whole point of animal studies to find out what happens when you inject this vaccine into a living being...

They haven't even disclosed what's in Comirnaty, which technically was 'approved' by the FDA. We can't even get that data, you know, so it makes it very very suspicious what's in there…

[L]et's just look at the spike protein. Alright, if this thing works the way it's supposed to, it's instructions for your body to make spike protein. What happens when you inject spike protein into animals? They have strokes, they have heart attacks, they develop myocarditis. It's a toxin, all right, and you're injecting instructions on how to make a toxin. We have no idea how long your body's gonna make that, we have no idea how much you're going to make…

If I inject you with this, **I have no idea what the toxin level is**. Because you might make this much toxin, this much spike, and I might make this much spike [*emphasis added*]. Right? So we have no idea. And that's the scary thing about this. And again, this is science, and nobody's even listening to this."

[333] **ADDED since 2/8/2022**
Video (2h:12m) Session 86 of the Corona Investigative Committee
January 7, 2022
https://odysee.com/@Corona-Investigative-Committee:5/Mike-Session-86-en:0

Starting at 42m:

Dr. Michael Yeadon: "I stumbled across a couple of people independently who'd been doing their own analysis of the VAERS database. What they were doing … was they were pulling the vaccine batch number or lot number… and comparing the profile of adverse events, comparing one lot to another lot to another lot, with the same manufacturer.

Their expectation would be a scattering of adverse events across all of the states, and all of the lots. But they didn't find that. This person found that something like 90% of the adverse events were associated with something like 10% of the lots…

If it's very different, I'm afraid I can tell you with certainty, I would be able to prove this mathematically if needed in court, it's not possible to go from two or three adverse events reported for a given lot, and another lot have 5,000 adverse events. It's not possible if you only vary the products a little bit.

If you go from nothing, effectively, to the worst outcomes ever reported to VAERS, **I am prepared to state** and **to prove** that that means it is not the same material in the lots that have produced bad side effects. Some of the vaccines contain something different and its definitely not the same stuff.'"

[334] ***The mRNA-LNP platform's lipid nanoparticle component used in preclinical vaccine studies is highly inflammatory***
iScience (Thomas Jefferson University)
Sonia Ndeupen, Zhen Qin, *et al*.
November 19, 2021
https://www.cell.com/iscience/fulltext/S2589-0042(21)01450-4

"**Summary**: Vaccines based on mRNA-containing lipid nanoparticles (LNPs) are a promising new platform used by two leading vaccines against COVID-19. Clinical trials and ongoing vaccinations present with varying degrees of protection levels and side effects. However, the drivers of the reported side effects remain poorly defined. Here we present evidence that Acuitas' LNPs used in preclinical nucleoside-modified mRNA vaccine studies are highly inflammatory in mice. Intradermal and intramuscular injection of these LNPs led to rapid and robust inflammatory responses, characterized by massive neutrophil infiltration, activation of diverse inflammatory pathways, and production of various inflammatory cytokines and chemokines. The same dose of LNP delivered intranasally led to similar inflammatory responses in the lung and resulted in a high mortality rate, with mechanism unresolved. Thus, the mRNA-LNP platforms' potency in supporting the induction of adaptive immune responses and **the observed side effects may stem from the LNPs' highly inflammatory nature**

[*emphasis added*] …

Results: … With the experiments presented earlier, we observed a high mortality rate among the mice inoculated with LNPs. These findings prompted us to perform a dose-response experiment to determine the amounts of LNPs that might be safe to use for mucosal vaccination. We intranasally inoculated adult WT B6 mice with LNPs ranging from 2.5 μg to 10 μg/mouse and monitored their health and weight for up to 8 days. We found that **~80% of mice treated with 10 μg of LNP died in less than 24 h** [*emphasis added*] (Figure 3D). The 5 μg dose killed ~20% of the mice by that time, whereas all the 2.5 μg-treated mice survived and showed no weight drop (Figure 3D) and no significant clinical signs of distress (Figure 3E). For the 5 and 10 μg doses, the surviving mice showed **notable clinical scores of distress**, such as shaking/shivering, and they lost weight significantly during the first 2 days of treatment (Figures 3E and 3F). After the first ~3 days, these mice did not continue to show significant clinical scores anymore, and their weight slowly started to normalize (Figure 3E)."

[335] **ADDED since 2/8/2020**

The EMA covid-19 data leak, and what it tells us about mRNA instability

British Medical Journal
Serena Tinari
March 10, 2021
https://www.bmj.com/content/372/bmj.n627

"As it conducted its analysis of the Pfizer-BioNTech covid-19 vaccine in December, the European Medicines Agency (EMA) was the victim of a cyberattack.1 More than 40 megabytes of classified information from the agency's review were published on the dark web, and several journalists—including from The BMJ—and academics worldwide were sent copies of the leaks...

The BMJ has reviewed the documents, which show that **regulators had major concerns over unexpectedly low quantities of intact mRNA in batches of the vaccine developed for commercial production**.

EMA scientists tasked with ensuring manufacturing quality—the chemistry, manufacturing, and control aspects of Pfizer's submission to the EMA—worried about 'truncated and modified mRNA species present in the finished product.' Among the many files leaked to The BMJ, an email dated 23 November by a high ranking EMA official outlined a raft of issues. In short, **commercial manufacturing was not producing vaccines to the specifications expected**, and regulators were unsure of the implications…

But the documents offer the broader medical community a chance to reflect on the complexities of quality assurance for novel mRNA vaccines, which include everything from the quantification and integrity of mRNA and carrier lipids to measuring the distribution of particle sizes and encapsulation efficiency. Of particular concern is RNA instability, one of the most important variables relevant to all mRNA vaccines that has thus far received scant attention in the clinical community. It is an issue relevant not just to Pfizer-BioNTech's vaccine but also to those produced by Moderna, CureVac, and others, as well as a 'second generation' mRNA vaccine being pursued by Imperial College London.

RNA instability is one of the biggest hurdles for researchers developing nucleic acid based vaccines. It is the primary reason for the technology's stringent cold chain requirements and has been addressed by encapsulating the mRNA in lipid nanoparticles…

In a rapid response posted on bmj.com, JW Ulm, a gene therapy specialist who has published on tissue targeting of therapeutic vectors, raised concerns about the biodistribution of LNPs: "At present, relatively little has been reported on the tissue localisation of the LNPs used to encase the SARS-CoV-2 spike protein-encoding messenger RNA, and it is vital to have more specific information on precisely where the liposomal nanoparticles are going after injection."

It is an unknown that Ulm worries could have implications for vaccine safety."

[336] **ADDED since 2/8/2020**

A cautionary note: Toxicity of polyethylene glycol 200 injected intraperitoneally into mice
SAGE Journals — University of Heidelberg, Germany
Wilko Thiele, Lenka Kyjacova, Almut Köhler, and Jonathan P. Sleeman
September 16, 2019
https://journals.sagepub.com/doi/10.1177/0023677219873684

"**Abstract**: The parenteral administration of hydrophobic substances in vivo requires the use of organic solvents to ensure sufficient solubility and avoid precipitation. Dimethyl sulfoxide is commonly used for this purpose. Based on the common assumption that polyethylene glycol (PEG) is non-toxic, our local regulatory authorities recently recommended the use of PEG instead. However, mice injected intraperitoneally (i.p.) with PEG 200 at a dose of 8 mL/kg (i.e. 9 g/kg) did not tolerate PEG 200 well, and **half of the animals had to be euthanized**. Our results demonstrate that although PEG 200 is generally considered to be harmless, it can be toxic when injected i.p. and is painful for the recipient mice. Nevertheless, it can be used as a solvent for repeated i.p. injections in mice at a dose of 2 mL/kg (i.e. 2.25 g/kg) without obvious signs of systemic toxicity."

[337] **ADDED since 2/8/2022**

Toxicity of cationic lipids and cationic polymers in gene delivery
Journal of Controlled Release — Dalian Nationalities University, China
Hongtao Lv, Shubiao Zhang, Bing Wang, Shaohui Cui, and Jie Yan
August 10, 2006
https://www.sciencedirect.com/science/article/abs/pii/S0168365906002045

"**Abstract**: Gene therapy, as a promising therapeutics to treat genetic or acquired diseases, has achieved exciting development in the past two decades. Appropriate gene vectors can be crucial for gene transfer. Cationic lipids and polymers, the most important non-viral vectors, have many advantages over viral ones as non-immunogenic, easy to produce and not oncogenic. They hold the promise to replace viral vectors to be used in clinic. However, the **toxicity is still an obstacle** to the application of non-viral vectors to gene therapy."

[338] **ADDED since 2/8/2022**
Cationic compounds used in lipoplexes and polyplexes for gene delivery
Journal of Controlled Release — Dalian Nationalities University, China
Shubiao Zhang, Yingmei Xu, Bing Wang, Weihong Qiao, Dongliang Liu, and Zongshi Li
November 24, 2004
https://www.sciencedirect.com/science/article/abs/pii/S0168365904004006

> "**Abstract**: Gene transfer represents an important advance in the treatment of both genetic and acquired diseases. Many cationic lipids and cationic polymers naturally occurred or synthesized have been used for gene transfer. They have the advantages over viral gene transfer as non-immunogenic, easy to produce and not oncogenic. These cationic compounds, however, have the major limitations of inefficient transfection and **toxicity to cells**."

Graphene Oxide

Notes:

- The citations below are presented in reverse, chronological order.
- As of December 22, 2022, the compiler of this document is unaware of conclusive evidence that graphene oxide is an ingredient in any of the COVID-19 inoculations, in part because the manufacturers have yet to provide full transparency. However, the materials below demonstrate that graphene oxide has been tested and used for biomedical purposes, including vaccination.

[339] ***Recent progress of graphene oxide as a potential vaccine carrier and adjuvant***
Acta Biomaterialia
Wanjun Cao, Lin He, *et al*.
August 2020
https://www.sciencedirect.com/science/article/abs/pii/S1742706120303305

> "**Abstract**: Vaccine is one of the most effective strategies for preventing and controlling infectious diseases and some noninfectious diseases, especially cancers. Adjuvants and carriers have been appropriately added to the vaccine formulation to improve the immunogenicity of the antigen and induce long-lasting immunity. However, there is an urgent need to develop new all-purpose adjuvants because some adjuvants approved for human use have limited functionality. Graphene oxide (GO), **widely employed for the delivery of biomolecules**, excels in loading and delivering antigen and shows the potentiality of activating the immune system. However, **GO aggregates in biological liquid and induces cell death**, and it also exhibits poor biosolubility and biocompatibility. To address these limitations, various surface modification protocols have been employed to integrate aqueous compatible substances with GO to effectively improve its biocompatibility. More importantly, these modifications render functionalized-GO with superior properties as both **carriers** and **adjuvants** [*emphasis added*]. Herein, the recent progress of physicochemical properties and surface modification strategies of GO for its application as both carriers and adjuvants is reviewed.

Statement of Significance

Due to its unique physicochemical properties, graphene oxide is widely employed in medicine for purposes of photothermal treatment of cancer, **drug delivery**, antibacterial therapy, and medical imaging [*emphasis added*]. Our work describes the surface modification of graphene oxide and for the first time summarizes that functionalized graphene oxide serves as a vaccine carrier and shows significant adjuvant activity in activating cellular and humoral immunity. In the future, it is expected to be introduced into vaccine research to improve the efficacy of vaccines."

[340] ***The new era of vaccines: the "nanovaccinology"***
European Review for Medical and Pharmacological Sciences (University of Messina, Italy)
A. Facciola, G. Visalli, *et al*.
August 2019
https://www.europeanreview.org/wp/wp-content/uploads/7163-7182.pdf

"**Abstract**: Vaccinations are the most effective preventive methods against infectious diseases and represent one of the most relevant successes of medicine. Vaccine development is constantly evolving; therefore, the number of vaccine candidates is progressively increasing. However, most of new potential vaccines are characterized by a lower immunogenicity, with the inability to stimulate powerful and long-lasting immune responses. Hence, to get modern and effective vaccines, we need of adjuvants and innovative delivery systems that increase their immunogenicity. The use of nanotechnology in vaccinology is providing the opportunity to contrast these difficulties and develop effective vaccines. Particularly, nanoparticles used as vehicles of vaccine components, are able to increase the host's immune responses and, due to their size, to reach specific cellular districts. To date, a certain number of nanovaccines has been approved for human health and many are studied in clinical or pre-clinical trials… In this review, we provide a general overview of different types, methods of synthesis, characterizations, properties and applications of nanoparticles in vaccine production…

Carbon Nanoparticles: Many studies have been conducted to evaluate the use of carbon nanomaterials as adjuvants or carriers for different kinds of vaccines especially because they are internalized into a wide variety of cell types156-160. Many structural and physical features of these nanosystems effect the capacity of carrying antigens and stimulating immune responses, among which their surface modifications.

Among carbon nanoparticles, carbon nanotubes (CNTs) have received a great attention because of their exceptional features that make them usable in many industrial fields. CNTs are engineered nanoparticles formed by a thick sheet of graphene that rolls up to form a hollow cylinder named single-walled CNT (SWCNT)."

[341] ***Graphene and graphene oxide as nanomaterials for medicine and biology application***
Journal of Nanostructure in Chemistry
Subhashree Priyadarsini, Swaraj Mohanty, *et al*.
June 7, 2018
https://link.springer.com/article/10.1007/s40097-018-0265-6

"**Abstract**: Graphene- and graphene oxide-based nanomaterials have gained broad interests in research because of their unique physiochemical properties. The 2D allotropic structure allows it to be used in various biological fields. The biomedical applications of graphene and its composite include its use in **gene** and **small molecular drug delivery** [*emphasis added*]. It is further used for biofunctionalization of protein, in anticancer therapy, as an antimicrobial agent for bone and teeth implantation. The biocompatibility of the newly synthesized nanomaterials allows its substantial use in medicine and biology."

[342] ***Graphene and the Immune System: A Romance of Many Dimensions***
Frontiers in Immunology
Sourav P. Mukherjee, Massimo Bottini, and Bengt Fadeel
June 13, 2017
https://www.frontiersin.org/articles/10.3389/fimmu.2017.00673/full

"Graphene-based materials (GBMs) are emerging as attractive materials for biomedical applications. Understanding how these materials are perceived by and interact with the immune system is of fundamental importance. Phagocytosis is a major mechanism deployed by the immune system to remove pathogens, particles, and cellular debris. Here, we discuss recent studies on the interactions of GBMs with different phagocytic cells, including macrophages, neutrophils, and dendritic cells…

Introduction: Graphene and its derivatives have attracted considerable attention for various applications in science and technology. Graphene oxide (GO), in particular, is being **intensively investigated for various biomedical applications including drug delivery** and bioimaging, and as biosensors."

[343] ***Toxicity of graphene-family nanoparticles: a general review of the origins and mechanisms***
Particle and Fibre Toxicology
Lingling Ou, Bin Song, *et al*.
October 31, 2016
https://particleandfibretoxicology.biomedcentral.com/articles/10.1186/s12989-016-0168-y

"**Abstract**: …We also point out that various factors determine the toxicity of GFNs [*graphene-family nanomaterials*] including the lateral size, surface structure, functionalization, charge, impurities, aggregations, and corona effect etc. In addition, **several typical mechanisms underlying GFN toxicity have been revealed**, for instance, physical destruction, oxidative stress, DNA damage, inflammatory response, apoptosis, autophagy, and necrosis [*emphasis added*]."

[344] ***Functionalized graphene oxide serves as a novel vaccine nano-adjuvant for robust stimulation of cellular immunity***
Soochow University (China)
Ligeng Xu, Jian Xiang, *et al*.
February 14, 2016
https://pubmed.ncbi.nlm.nih.gov/26814441/

> "**Abstract**: … Benefiting from their unique physicochemical properties, graphene derivatives have attracted great attention in biomedicine. In this study, we carefully engineered graphene oxide (GO) as a vaccine adjuvant for immunotherapy using urease B (Ure B) as the model antigen… Our work not only presents a **novel**, **highly effective GO-based vaccine nano-adjuvant**, but also highlights the critical roles of surface chemistry for the rational design of nano-adjuvants [*emphasis added*]."

Biodistribution of COVID-19 Vaccines

Note: The citations below are presented in reverse, chronological order.

[345] **ADDED since 2/8/2022**
Research Letter: *Detection of Messenger RNA COVID-19 Vaccines in Human Breast Milk*
JAMA Pediatrics — NYU Long Island School of Medicine
Nazeeh Hanna, Ari Heffes-Doon, *et al*.
September 26, 2022
https://jamanetwork.com/journals/jamapediatrics/fullarticle/2796427

> "The Centers for Disease Control and Prevention recommends offering the COVID-19 mRNA vaccines to breastfeeding individuals,3 although the possible passage of vaccine mRNAs in breast milk resulting in infants' exposure at younger than 6 months was not investigated. This study investigated whether the COVID-19 vaccine mRNA can be detected in the expressed breast milk (EBM) of lactating individuals receiving the vaccination within 6 months after delivery…
>
> **Results**: Of 11 lactating individuals enrolled, **trace amounts of BNT162b2** and **mRNA-1273 COVID-19 mRNA vaccines were detected in 7 samples** from 5 different participants at various times up to 45 hours postvaccination…
>
> **Discussion**: … These data demonstrate for the first time to our knowledge the biodistribution of COVID-19 vaccine mRNA to mammary cells and the potential ability of tissue EVs to package the vaccine mRNA that can be transported to distant cells. Little has been reported on lipid nanoparticle biodistribution and localization in human tissues after COVID-19 mRNA vaccination. In rats, up to 3 days following intramuscular administration, low vaccine mRNA levels were detected in the **heart**, **lung**, **testis**, and **brain tissues**, indicating tissue biodistribution. We speculate that, following the vaccine administration, lipid nanoparticles containing the vaccine mRNA are carried to mammary glands via hematogenous and/or lymphatic routes. Furthermore, we speculate that vaccine mRNA released into mammary cell cytosol can be recruited into developing EVs that are later secreted in EBM."

[346] **ADDED since 2/8/2022**

Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination

Biomedicines — National Institute of Pathology, Romania
Tudor Emanuel fertic, Leona Chitoiu, *et al*.
June 28, 2022
https://www.mdpi.com/2227-9059/10/7/1538

> "**Abstract**: COVID-19 mRNA vaccines effectively reduce incidence of severe disease, hospitalisation and death. The biodistribution and pharmacokinetics of the mRNA-containing lipid nanoparticles (LNPs) in these vaccines are **unknown in humans**. In this study, we used qPCR to track circulating mRNA in blood at different time-points after BNT162b2 vaccination in a small cohort of healthy individuals. We found that vaccine-associated synthetic mRNA persists in systemic circulation for **at least 2 weeks**. Furthermore, we used transmission electron microscopy (TEM) to investigate SARS-CoV-2 spike protein expression in human leukemic cells and in primary mononuclear blood cells treated in vitro with the BNT162b2 vaccine. TEM revealed morphological changes suggestive of LNP uptake, but only a small fraction of K562 leukemic cells presented spike-like structures at the cell surface, suggesting reduced levels of expression for these specific phenotypes."

[347] **Audio interview (8m): *Dr. Byram Bridle Professor of Viral Immunology on Spike Protein***
May 31, 2021
https://odysee.com/@Jay:46/dr-byram-bridle-professor-of-viral:e
Video (13m): Dr Byram Bridle at press conference held by Derek Sloan (Canadian Member of Parliament), June 17, 2021
https://odysee.com/@stonemonkey:c/byram:e

> "I'm going to walk you through this… Everything I'm stating here is completely backed up by peer-reviewed, scientific publications in well-known, well-respected scientific journals… What has been discovered by the scientific community is the spike protein, on its own, is almost entirely responsible for the damage to the cardio-vascular system, if it gets into circulation. Indeed, if you inject the purified spike protein into the blood of research animals, they get all kinds of damage to the cardio-vascular system, it can cross the blood-brain barrier and cause damage to the brain... The assumption, all up until now, is that these vaccines behave like all of our traditional vaccines, that they don't go anywhere other than the injection site. So they stay in our shoulder. Some of the protein will go to the local draining lymph node, in order to activate the immune system. However, this is where the cutting-edge science is coming in. This is where it gets scary.
>
> Through a request for information from the Japanese regulatory agency, myself and several international collaborators have been able to get access to what's called a bio-distribution study. It's the first time ever that scientists have been privy to seeing where these messenger mRNA vaccines go after vaccination. In other words, is it a safe assumption that it stays in the shoulder muscle? The short answer is, absolutely not. It's very disconcerting. The spike protein gets into the blood, circulates through the blood in individuals, over several days post-vaccination. Once it gets in the blood, it accumulates in a number of tissues, such as the spleen, the bone marrow, the liver, the adrenal glands... **One that's of particular concern for me is it accumulates in quite high concentrations in the ovaries**. And then also a (scientific paper) that was just accepted for publication that backs this up looked at 13 young healthcare workers that had received the Moderna vaccine… (and) they found the spike

protein in circulation, so in the blood of 11 of those 13 healthcare workers who had received the vaccine…

Now we have clear-cut evidence that the vaccines that make our bodies… manufacture this protein, the vaccine itself plus the protein gets into blood circulation. When in circulation, the spike protein combined to the receptors that are on our platelets and the cells that line our blood vessels. When that happens, it can do one of two things – It can either cause platelets to clump, and that can lead to clotting, and that's exactly why we've been seeing clotting disorders associated with these vaccines. It can also lead to bleeding and, of course, the heart's involved… That's why we're seeing heart problems. The protein can also cross the blood-brain barrier and cause neurological damage. That's why also in fatal cases of blood clots, many times it's seen in the brain…

In short, the conclusion is, we made a big mistake, we didn't realize it until now. We thought the spike protein was a great target antigen. We never knew the spike protein itself was a toxin and a pathogenic protein. **So by vaccinating people, we are inadvertently inoculating them with a toxin** [*emphasis added*]."

SARS-COV-2 mRNA Vaccine (BNT162, PF-07302048) 2.6.4 - Overview of Pharmacokinetic Test
Pfizer, Inc.
Note: Allegedly, this is the Pfizer animal study acquired by Dr. Byram Bridle and colleagues (see [347]) from a Japanese regulatory agency that appears to show Pfizer knew their COVID-19 vaccine 1) circulates in the bloodstream following intravenous administration, and 2) deposits constituent lipids in the liver, ovaries, and other organs. Authors and date unknown.
https://archive.org/details/pfizer-confidential-translated/page/n2/mode/1up

"**4. Distribution**: … Total recoveries of radioactivity relative to the dose outside of the dose site were highest in the liver (up to 18%) and were significantly lower in the spleen (<1.0%), adrenal glands (<0.11%), and ovaries (<0.095%) than in the liver."

[348] **ADDED since 2/8/2022**
2.4 Nonclinical Overview AZD1222
AstraZeneca
April 26, 2021
https://icandecide.org/wp-content/uploads/2022/11/2022-10-24-IR0751D_Production_MHRA_000001-000166-166-pages.pdf#page=36
Note: This document was acquired with FOIA request submitted by the Informed Consent Action Network (ICAN) to the United Kingdom's FDA equivalent – the Medicines and Healthcare Products Registry Agency (MHRA) -- in April 2022. The request sought information relating to the MHRA's authorization of the AstraZeneca, Janssen, Moderna, and Pfizer COVID-19 vaccines.

"**3.2 Distribution**…

In an AZD1222 biodistribution study in mice, there was no biodistribution to blood and faeces samples with the exception of low signal from 2 blood and 1 faeces samples on Day 2. Both blood samples had signals below the limit of quantification (<LLOQ) and the faeces sample returned a low signal of 1.30 x 103 copies/µg DNA (LLOQ was 50 copies/Q-PCR reaction). In tissues, **AZD1222 vector DNA showed biodistribution** to the intramuscular administration sites, sciatic nerve, bone marrow, liver, lung and spleen. The highest levels of AZD1222 vector

DNA (103 to 107 copies/µg DNA) were observed in the intramuscular administration sites and sciatic nerve (close proximity to the administration sites) on Day 2. Lower levels of AZD1222 vector DNA (<LLOQ to 104 copies/µg DNA) were observed in bone marrow, liver, spleen and lung, on Day 2. The levels of AZD1222 and the number of tissues with detectable levels of AZD1222 vector DNA decreased from Day 2 to 29, indicating elimination."

[349] ***First case of postmortem study in a patient vaccinated against SARS-CoV-2***
International Journal of Infectious Diseases
Torsten Hansen, Ulf Titze, *et al*.
April 16, 2021
https://www.ijidonline.com/article/S1201-9712(21)00364-7/fulltext

"**Highlights**:

- We report on a patient with a single dose of vaccine against SARS-CoV-2.
- He developed relevant serum titer levels but died 4 weeks later.
- By postmortem molecular mapping, **we found viral RNA in nearly all organs examined**.
- However, we did not observe any characteristic morphological features of COVID-19. [*emphasis added*]
- Immunogenicity might be elicited, while sterile immunity was not established."

[350] **ADDED since 2/8/2022**
Nonclinical Evaluation Report: BNT162b2 [mRNA] COVID-19 vaccine (COMIRNATY™)
Australian Government Department of Health (Therapeutic Goods Administration)
Result of a Freedom of Information Request
January 2021
https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf

"**Pharmacokinetics:** Pharmacokinetic studies are generally not required for a vaccine per relevant guidelines; however, they are recommended for novel excipients or adjuvants used in the vaccine formulation, and in some cases for the antigen. The LNP in BNT162b2 contains two novel excipients, pharmacokinetics of which were studied in animal species and *in vitro*. In addition, tissue distribution of luciferase expressed by luciferase-encoding mRNA as **a surrogate of the vaccine mRNA** in the LNP formulation was also studied…

4.2.2. Study 185350

The distribution of lipid nanoparticles (containing ALC-0315 and ALC-0159) encapsulating mRNA encoding luciferase, was investigated by monitoring of a radiolabelled (3H-) lipid-marker after IM administration to Wistar rats.

Study details

Lipid nanoparticle formulation [LNP size, lipid composition (relative to mRNA concentration), and encapsulation efficiency similar to LNP in BNT162b2 vaccine] along with trace amounts of radiolabelled lipid marker cholesteryl-1,2-3H(N)]-cholesteryl hexadecyl ether (Figure 4-6), was administered intramuscularly to 42 Wistar Han rats (21/sex; 8-11 week age) at a target dose

of 50 µg mRNA/animal (1.29 mg total lipid/animal)…

Tissue distribution

- The concentration of radioactive lipid marker reached the peak level in plasma (8.9 µg lipid eqv/mL) between 1 – 4 h post-dose and distribution mainly into liver, adrenal glands, spleen and ovaries over 48 h (Table 4-2). The concentration of radioactivity remained highest in injection site at all time-points…
- Mean total radioactivity was greatest at the injection site followed by the liver with much lower total recovery in spleen, adrenal glands and ovaries (Table 4-2)…

Conclusions

- Slow but **significant distribution of lipid nanoparticles** from the site of injection with major uptake into **liver**.
- Minor distribution in **spleen**, **adrenal glands** and **ovaries** over 48 h.
- Mean blood:plasma ratios of 0.5-0.6 indicating nanoparticles mainly present in plasma fraction of blood with peak concentrations in plasma at approx. 2 h post-dose."

Table 4-2. Mean concentration of radioactivity (sexes combined) in tissue and blood following a single IM dose of 50 µg mRNA/rat

Sample	Total Lipid Concentration (µg lipid equiv/g (or mL))						
	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181
Adrenal glands	0.27	1.48	2.72	2.89	6.80	13.77	18.21
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687
Bone marrow (femur)	0.48	0.96	1.24	1.24	1.84	2.49	3.77
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112
Heart	0.28	1.03	1.40	0.99	0.79	0.45	0.55
Injection site	128.3	393.8	311.2	338.0	212.8	194.9	164.9
Kidneys	0.39	1.16	2.05	0.92	0.59	0.43	0.42
Large intestine	0.013	0.048	0.09	0.29	0.65	1.10	1.34
Liver	0.74	4.62	10.97	16.55	26.54	19.24	24.29
Lung	0.49	1.21	1.83	1.50	1.15	1.04	1.09
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.366
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.26
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253
Small intestine	0.030	0.221	0.476	0.879	1.279	1.302	1.472
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112
Spleen	0.33	2.47	7.73	10.30	22.09	20.08	23.35
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.000
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456
Whole blood	1.97	4.37	5.40	3.05	1.31	0.91	0.42
Plasma	3.96	8.13	8.90	6.50	2.36	1.78	0.81
Blood:plasma ratio	0.815	0.515	0.550	0.510	0.555	0.530	0.540

[351] **ADDED since 2/8/2020**

Rapid Response — *re. Will covid-19 vaccines save lives? Current trials aren't designed to tell us*

British Medical Journal
JW Ulm, MD/PhD
October 21, 2020
https://www.bmj.com/content/371/bmj.m4037/rr-19

"Peter Doshi's nuanced article has opened up a rigorous and valuable discussion about the ongoing COVID-19 mRNA vaccine clinical trials, and I would like to home in on what is perhaps the most salient source of concern about their efficacy and safety, and a key step in building public confidence: the need for extensive data on the vaccines' cellular tropism and MHC Class I vs. MHC Class II-mediated antigen presentation, with attendant questions about potential seeding of autoimmunity. The mRNA vaccines' nucleic acid payload is ferried into human cells via complex lipid nanoparticles (LNPs) with a lipophilic formulation capable of traversing phospholipid bilayers, through endocytosis and other mechanisms [1]. While some LNP vehicles have been engineered with specific tropisms for target tissues, others have less selective tropisms (or are even potentially omnitropic), capable of entering diverse cell types [2]. From studies thus far, it remains unclear under which category the LNPs used in the COVID vaccine trials appear to fall, and this point is essential for gauging long-term safety and efficacy. If these LNPs have a broad cell tropism, **then they would be capable of entering and expressing the SARS-CoV-2 viral spike protein within the parenchyma of vital organs and tissues**, well beyond the tropism of wild-type coronavirus. The resulting non-self protein, presented to immune surveillance via MHC-I complexes, would trigger a cytotoxic (CD8-mediated) immune response to the expressing cells, which could with time engender clinically significant tissue damage…

At present, relatively little has been reported on the tissue localization of the LNPs used to encase the SARS-CoV-2 spike protein-encoding messenger RNA, and **it is vital to have more specific information on precisely where the liposomal nanoparticles are going after injection**, both in concurrent animal studies and in the two ongoing mRNA vaccine human trials. This process can be commenced in straightforward fashion through cell culture and animal-based investigations, by supplying mRNA expressing a fluorophoric reporter gene (such as green fluorescent protein) delivered via the same LNP formulations as used in the two vaccine trials, and tracking its ingress into varied cells and tissues. The mRNA vaccines represent a remarkable and promising technology, with potential to expedite the development of immunization protocols for future epidemics, but this promise will evaporate if unanticipated safety issues and side effects emerge to weaken public trust in the new modality. Cellular and tissue localization data on the vaccines' tissue tropisms, obtained and confirmed across multiple independent laboratories, would constitute a valuable step to reinforce public confidence in this regard."

Credentialed Opposition to further Distribution of COVID-19 Vaccines

Note: The citations below are presented in reverse, chronological order.

[352] **ADDED since 2/8/2022**
Health Reform Declaration
Australian Medical Professionals' Society
Updated with signatories as of April 3, 2023
https://amps.redunion.com.au/healthreformdeclaration

"Dear Senator/Member,

A Declaration and Urgent Demands: Parliamentary Health Reform Package…

We are a group of medical and scientific professionals who hold concerns regarding the overreach of government control on the freedom of the medical and scientific community, to freely debate medical treatments. The persons to this declaration, hold the view that some or all the following topics and/or these statements are correct, and should be open for public debate by all persons in the profession, without restriction or repercussions:

1. Experimental, inadequately tested medical products were given Provisional Approval. These were not traditional vaccines but new technology with a new mode of action…

2. Despite the Provisional Approval and incomplete data, the public were falsely assured all processes had been followed, and the products were repeatedly pronounced as 'Safe and Effective' by Public Health figures and politicians.

3. Effective and cheap off-label drugs for preventing or treating Covid-19 were banned by the TGA. Doctors who used these medicines were subject to legal action and de-registration.

4. No proactive monitoring process to collect safety signals from the injections was put in place in line with the gene therapy 'vaccine' roll out.

5. These gene therapy injections did not have the advertised 95% reduction in infection. In fact, there was no significant reduction in infection…

7. Serious side effects began to turn up for medical practitioners. Patients have myocarditis/pericarditis, reactivation of cancers, DNA viruses, myocardial infarctions, strokes, and fatigue syndromes. Hundreds more symptoms and injuries are being reported…

11. The unprecedented number of reports of death, illness, and injury from the 'vaccines' in the TGA DAEN system continue to be ignored. Post-mortems were not mandated for these experimental injections. **Deaths associated with the 'vaccines' continue to be dismissed without post-mortem or pathologic assessment**…

The attached proposed amendments to the Therapeutic Goods Act and Health Practitioner Regulation National Law will reduce these unfortunate and preventable outcomes.

We, the below signatories, being Australian health practitioners and scientists, urgently demand through the enactment of the proposed amendments: …"

[353] **ADDED since 2/8/2022**

Statement From Medical Professionals Supporting Parental Rights and Medical Freedom
January 2023
Signatories (1,000+): https://childrenshealthdefense.org/sign
https://childrenshealthdefense.org/wp-content/uploads/CHD-letter-from-doctors-to-lawmakers.pdf

"**Executive Summary**

1. There is no scientific rationale for continuing any COVID-19 mandates in 2023 and beyond.
2. Mask and vaccine exemptions must be offered at the discretion of the physician and patient as opposed to one-size-fits-all government edicts.
3. Parental rights and decisions must be preserved to ensure the health and well-being of their children.
4. The ability of medical professionals to speak freely to their patients and the public must not be compromised."

[354] **ADDED since 2/8/2022**

Video (2m): *It's time to withdraw the mRNA vacines*
Dr. Joseph Fraiman
January 9, 2023
https://rumble.com/v24k8be-its-time-to-withdraw-the-mrna-vaccines.html

"Hello. My name is Dr. Joseph Fraiman. I'm an emergency physician based in Louisiana. In addition, I am a clinical scientist.

I was lead author of the peer-reviewed study that re-analyzed the original Pfizer and Moderna clinical trials for the messenger RNA COVID-19 vaccines. We found the vaccine increased serious adverse events at a rate of 1 in 800.

At the time of publication, my co-authors and I did not believe our single study warranted the withdrawal of the messenger RNA vaccines from the market. However, since its publication, multiple new pieces of evidence have come to light, and this has caused me to re-evaluate my position…

In addition, now we have multiple autopsy studies that find essentially conclusive evidence that the vaccines are inducing sudden cardiac deaths...

While many nations that have been using the messenger-RNA vaccines have experienced an increase in excess mortality, more people dying than should be expected from past years. And this correlates in time with the initial vaccine rollout, and then with the subsequent booster campaigns…

Together, this information calls into question that the vaccine's benefits are outweighing the harm. I believe, given the information, the **messenger-RNA vaccines need to be withdrawn** from the market until new randomized, controlled trials can clearly demonstrate the benefits of the vaccines outweigh the serious harm we now know the vaccines are causing."

[355] **ADDED since 2/8/2022**
Video (4m): *Time to pause covid mass vaccination*
Dr. John Campbell
December 28, 2022
https://rumble.com/v22ugd2-time-to-pause-covid-mass-vaccination.html

"My name is John Campbell, I am a semi-retired clinical nurse, nurse lecturer, academic, researcher and author of numerous articles and two text books.

My specialisms are human physiology and pathophysiology, as applied to clinical practice. I have also produced many educational videos which are used extensively around the world.

In my view the UK health authorities should pause the current covid-19 vaccination programme, due to the risks associated with vaccination."

[356] **ADDED since 2/8/2022**
Video (18m): *UK Doctors Call For Government To Urgently Pause and Investigate the Use of Novel mRNA Covid Vaccines*
Doctors for Paitents (UK)
December 21, 2022
https://doctorsforpatientsuk.com/press-release/
About Us: "Doctors for Patients UK (DfPUK) was established in September 2022 and has become a fast-growing group of UK doctors dedicated to practising evidence-based, ethical and patient-centred medicine. Our group is borne out of increasing concerns that core principles of medical ethics are being disregarded, such as the oath to 'First do no harm', the respect for individual bodily autonomy and the need to obtain fully informed consent for all medical interventions."

Video testimonials from 17 medical professionals in the UK expressing their concerns and observations regarding the mRNA COVID-19 innoculations.

"Our members created this video as they felt the need to voice their perspectives, clinical experiences and serious ethical concerns. This was done in hope that our message is received and acknowledged by the relevant authorities with prompt and appropriate action taken."

[357] **ADDED since 2/8/2022**
Video (1m): *Statement by Dr. Ahmad K. Malik, MBChB, FRCS(Tr & Orth)*
December 15, 2022
https://twitter.com/mottomeneki/status/1601675590561837056

"Over the past couple of years, we've seen increasing people with injuries, with adverse side effects, an increasing number of cancers, neurological conditions, heart disease, clots…

We really need to suspend the rollout of these vaccines. We need to stop and do a proper investigation to find out what is going on."

[358] **ADDED since 2/8/2022**

Video (2m): *Statement by Dr. Dean Patterson*

December 10, 2022

https://twitter.com/mottomeneki/status/1601675590561837056

> "I am a consultant, general physician, and cardiologist. Since the COVID vaccines have been launched, I have noticed and increasing signal of myocarditis and myocardial injury. In conjunction with this, I have noticed an increasing signal of thrombosis and other serious adverse events…
>
> In light of my serious concerns, I believe we should halt the rollout of the vaccination program and perform a thorough investigation into the serious adverse events. Afterall, the preliminary study that have been done on these vaccines are yet to be completed in 2023, and almost the entire placebo group in these studies has now been vaccinated, making extrapolation of the harms extremely difficult.
>
> At present, we're seeing a wave of non-COVID excess mortality, which brings me to my conclusion that there is serious harm in association with the vaccine rollout and, until proven otherwise, these vaccines are not safe.

[359] **ADDED since 2/8/2022**

COVID-19 vaccine boosters for young adults: a risk benefit assessment and ethical analysis of mandate policies at universities

British Medical Journal — Journal of Medical Ethics

Kevin Bardosh, Allison Krug, *et al*.

December 5, 2022

https://jme.bmj.com/content/early/2022/12/05/jme-2022-108449

> "**Abstract**: In 2022, students at North American universities with third-dose COVID-19 vaccine mandates risk disenrolment if unvaccinated. To assess the appropriateness of booster mandates in this age group, we combine empirical risk-benefit assessment and ethical analysis. To prevent one COVID-19 hospitalisation over a 6-month period, we estimate that 31,207–42,836 young adults aged 18–29 years must receive a third mRNA vaccine. Booster mandates in young adults are expected to cause a net harm: **per COVID-19 hospitalisation prevented, we anticipate at least 18.5 serious adverse events from mRNA vaccines**, including 1.5–4.6 booster-associated myopericarditis cases in males (typically requiring hospitalisation). We also anticipate 1430–4626 cases of grade ≥3 reactogenicity interfering with daily activities (although typically not requiring hospitalisation). **University booster mandates are unethical** because they:
>
> (1) are not based on an updated (Omicron era) stratified risk-benefit assessment for this age group;
>
> (2) may result in a net harm to healthy young adults;
>
> (3) are not proportionate: expected harms are not outweighed by public health benefits given modest and transient effectiveness of vaccines against transmission;
>
> (4) violate the reciprocity principle because serious vaccine-related harms are not reliably compensated due to gaps in vaccine injury schemes; and

(5) may result in wider social harms.

We consider counterarguments including efforts to increase safety on campus but find these are fraught with limitations and little scientific support. Finally, we discuss the policy relevance of our analysis for primary series COVID-19 vaccine mandates."

[360] **ADDED since 2/8/2022**

Video: *Japanese Professor Upends Ministry of Health: Disband Vax Committee, Investigate All Injuries*

December 1, 2022

https://vigilantfox.substack.com/p/japanese-professor-goes-nuclear-on

Dr. Masonori Fukushima "is a Professor Emeritus at Kyoto University and Director and Chairman of Translational Research Informatics Center (TRI), Japan. An oncologist, he has over 25 years' experience engaging in the practice and dissemination of standard cancer treatment and reforming Japan's medical care system."

https://biography.omicsonline.org/united-states-of-america/cdisc/masanori-fukushima-300985

Fukushima addressing Japan's Ministry of Health: "Immediately dissolve the evaluation committee and investigate all cases. This is the conclusion. Investigate all cases! Everybody that received the vaccine then felt worse; everyone notify medical institutions. We can't be dragging our feet. Cardiovascular disease, autoimmune disease, susceptibility to infections, it will all go to the brain. Nanoparticles will be absorbed by the brain. The scientists that are dumb will say, 'They can't cross the blood barrier, so it's okay.' I want to say, 'You must be stupid.' Natural immunity is being suppressed. The reason why it didn't spread in Japan at first was because they have IgA in their saliva, and they have this resistance to Corona. However, due to the vaccine, natural immunity has been **shut down**. Natural immunity was suppressed; that's why this happened. It won't subside at all. It will spread more and more.

Did you calculate the breakthrough infections? Most people were breakthrough infections. It's not the unvaccinated that are infected. **It's the vaccinated that infect each other**. The Ministry of Health and Labor publicized data that clarifies all of this. I will speak on this later…

This vaccine, we don't know the long-term effects. Many **nanoparticles absorbed into the body will ceaselessly produce spike proteins**. People will wonder why they feel progressively more ill. Suddenly, gets worse. Blood pressure spikes out of nowhere. Eczema out of nowhere. When we investigate, we find spike proteins. But at this point of diagnosis, it has already moved into the next phase. We need to immediately stop vaccinations and take care of the health of all these cases. That's what this article says!"

[361] **ADDED since 2/8/2022**

Cardiologist calls for an end to mNRA booster shots - as teen, 18, tells how her reaction to the jab saw her miss her Year 12 exams: 'I've had 60 to 70 in my practice who've had similar reactions'

Daily Mail
Kevin Airs
November 24, 2022
https://www.dailymail.co.uk/news/article-11464097/Covid-Australia-2022-Teen-misses-HSC-pericarditis-jab-reaction-cardiologist-issues-warning.html

> "[A] Sydney cardiologist has called for an end to the use of mRNA vaccines like Pfizer and Moderna, after seeing a rise in jab-related heart conditions…
>
> 'Getting Covid is ten times worse than getting vaccinated - but we don't need to use mRNA vaccines like Pfizer and Moderna,' cardiologist Dr Ross Walker told Daily Mail Australia.
>
> 'We have to put COVID in perspective where it is right now, not where it was 12 months ago, because it has changed and I think we are seeing a change.'
>
> 'I've seen many people getting vaccine reactions, who get symptoms for about three to six months afterwards."
>
> 'I've seen 60-70 patients in my own practice over the past 12 months who have had similar reactions.'
>
> 'I've seen other people with chest pain, shortness of breath, heart palpitations.'…
>
> 'These mRNA vaccines are very pro-inflammatory,' said Dr Walker."

[362] **ADDED since 2/8/2022**

Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 2

Journal of Insulin Resistance
Aseem Molhotra, Cardiology MSc examiner at the University of Hertfordshire, UK
September 26, 2022
https://insulinresistance.org/index.php/jir/article/view/71/221

> "**Background**: Authorities and sections of the medical profession have supported unethical, coercive, and misinformed policies such as vaccine mandates and vaccine passports, undermining the principles of ethical evidence-based medical practice and informed consent. These regrettable actions are a symptom of the 'medical information mess': The tip of a mortality iceberg where prescribed medications are estimated to be the third most common cause of death globally after heart disease and cancer.
>
> **Aim**: To identify the major root causes of these public health failures.
>
> **Methods**: A narrative review of both current and historical driving factors that underpin the pandemic of medical misinformation.
>
> **Results**: Underlying causes for this failure include regulatory capture – guardians that are supposed to protect the public are in fact funded by the corporations that stand to gain from the sale of those medications. A failure of public health messaging has also resulted in wanton

waste of resources and a missed opportunity to help individuals lead healthier lives with relatively simple – and low cost – lifestyle changes.

Conclusion: There is a strong **scientific, ethical and moral case** to be made that the current COVID vaccine administration **must stop** until all the raw data has been subjected to fully independent scrutiny. Looking to the future the medical and public health professions must recognise these failings and eschew the tainted dollar of the medical-industrial complex. It will take a lot of time and effort to rebuild trust in these institutions, but the health – of both humanity and the medical profession – depends on it.

Contribution: This article highlights the importance of addressing metabolic health to reduce chronic disease and that insulin resistance is also a major risk factor for poor outcomes from COVID-19."

[363] **ADDED since 2/8/2022**
Audio (13m): Dr. Scott Youngblood presentation to the San Diego City Council
September 16, 2022
https://rumble.com/v1le649-dr.-scot-youngblood-makes-a-compelling-science-backed-case-against-covid-in.html

Youngblood: "I would like to present evidence today that the vaccine mandates, enabled by the state of emergency, may actually be making things worse….

In conclusion, we are not going to be able to vaccinate our way out of this pandemic. With enough time, the risk of infection and disease is **higher** among the vaccinated. Worse still, vaccinations may potentially **poison our natural immunity**."

[364] **ADDED since 2/8/2022**
COVID-19 Vaccine Boosters for Young Adults: A Risk-Benefit Assessment and Five Ethical Arguments against Mandates at Universities
Journal of Medical Ethics
Kevin Bardosh, Allison Krug, *et al*.
September 12, 2022
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4206070

"**Abstract**: Students at North American universities risk disenrollment due to third dose COVID-19 vaccine mandates. We present a risk-benefit assessment of boosters in this age group and provide five ethical arguments against mandates. We estimate that 22,000 - 30,000 previously uninfected adults aged 18-29 must be boosted with an mRNA vaccine **to prevent one COVID-19 hospitalisation**. Using CDC and sponsor-reported adverse event data, we find that booster mandates may cause a net expected harm: **per COVID-19 hospitalisation prevented in previously uninfected young adults, we anticipate 18 to 98 serious adverse events**, including 1.7 to 3.0 booster-associated myocarditis cases in males, and 1,373 to 3,234 cases of grade ≥3 reactogenicity which interferes with daily activities. Given the high prevalence of post-infection immunity, this risk-benefit profile is even less favourable. University booster mandates are **unethical** because: 1) no formal risk-benefit assessment exists for this age group; 2) vaccine mandates may result in a net expected harm to individual young people; 3) mandates are not proportionate: expected harms are not outweighed by public health benefits given the modest and transient effectiveness of vaccines against transmission; 4) US mandates violate the reciprocity principle because rare serious vaccine-

related harms will not be reliably compensated due to gaps in current vaccine injury schemes; and 5) mandates create wider social harms. We consider counter-arguments such as a desire for socialisation and safety and show that such arguments lack scientific and/or ethical support. Finally, we discuss the relevance of our analysis for current 2-dose COVID-19 vaccine mandates in North America."

[365] **ADDED since 2/8/2022**

Press Release: *Independent Pharmacovigilance Report Confirms Evidence for Recall of Covid-19 Vaccines*

World Council for Health (WCH)

June 11, 2022

https://worldcouncilforhealth.org/news/independent-pharmacovigilance-report-recall-of-covid-19-vaccines/

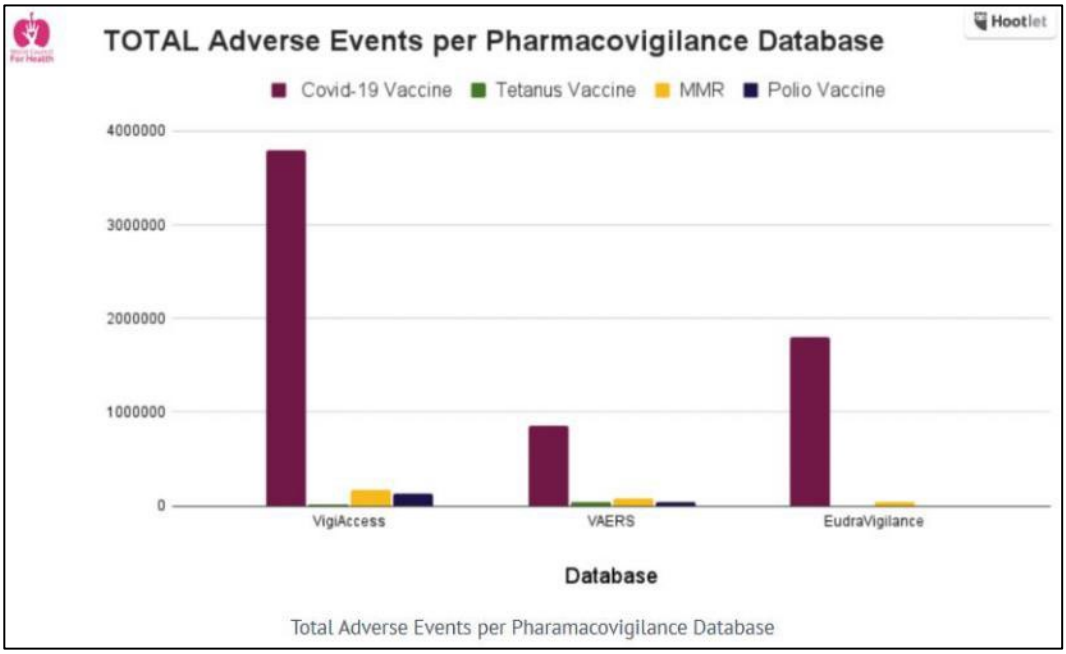
Covid-19 Vaccine Pharmacovigilance Report

https://worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report/

"A new report prepared by the World Council for Health (WCH) has confirmed that data on adverse drug reactions from the experimental Covid-19 vaccines exist in an amount sufficient for the recall of similar products in the past.

The report was prepared to determine whether sufficient pharmacovigilance data exist on official and public databases (WHO VigiAccess, CDC VAERS, EudraVigilance, and UK Yellow Card Scheme) to establish a safety signal on the novel Covid-19 injections.

On all databases, it was found that adverse drug reaction (ADR) reports linked to Covid-19 injections are more numerous than other similar products **by a factor of between 10 and 169** (see graph below). Many of the ADR reports are serious in nature and there exists sufficient evidence of associated harm on these databases to indicate a product recall."



[366] **ADDED since 2/8/2022**

Deaths Following C-19 Vaccination: An open letter from NZDSOS on the Need to Investigate Deaths Following Vaccination

New Zealand Doctors Speaking Out With Science
May 24, 2022
https://nzdsos.com/2022/05/24/deaths-following-c-19-vaccination/

"**Executive Summary**

1. There is a **shockingly large burden of deaths and injuries following the Covid-19 vaccines**, of itself and compared to any other treatment or vaccine in modern times. We report many cases that DEMAND proper investigation, as befits any medication lacking safety studies.

2. Our surveillance systems have been disabled in order to hide the extent of harm. Adverse event reporting is NOT COMPULSORY, and this alone undermines any attempt to portray the injections as safe. CARM was never designed to early warn about experimental drugs rolled out to massive numbers.

3. Children and young people are dying and suffering particularly cardiac injuries (though many healthy elderly have died too), whilst their risk from covid-19 is particularly low. We believe we are being lied to. We present many cases halfway down this post.

4. We appeal AGAIN to the Police, headed by Andrew Coster, and our MPs, to intervene to protect the People…

There is an evolving humanitarian crisis, and the government, Police, vaccine industry and most doctors are lost at sea.

For God's sake, people, let's make our Police and MPs put a stop to this now!"

[367] **ADDED since 2/8/2022**

Declaration IV - Restore Scientific Integrity: A Joint Statement, representing 17,000 Physicians and Medical Scientists to end the National Emergency, Restore Scientific Integrity, and Address Crimes Against Humanity

Global Covid Summit
May 11, 2022
https://globalcovidsummit.org/news/declaration-iv-restore-scientific-integrity

"After two years of scientific research, millions of patients treated, hundreds of clinical trials performed and scientific data shared, we have demonstrated and documented our success in understanding and combating COVID-19. In considering the risks versus benefits of major policy decisions, our Global COVID Summit of 17,000 physicians and medical scientists from all over the world have reached consensus on the following foundational principles:

1. We declare and the data confirm that the COVID-19 experimental genetic therapy injections must end.
2. We declare doctors should not be blocked from providing life-saving medical treatment.
3. We declare the state of national emergency, which facilitates corruption and extends the pandemic, should be immediately terminated.

4. We declare medical privacy should never again be violated, and all travel and social restrictions must cease.
5. We declare masks are not and have never been effective protection against an airborne respiratory virus in the community setting.
6. We declare funding and research must be established for vaccination damage, death and suffering.
7. We declare no opportunity should be denied, including education, career, military service or medical treatment, over unwillingness to take an injection.
8. We declare that first amendment violations and medical censorship by government, technology and media companies should cease, and the Bill of Rights be upheld.
9. We declare that Pfizer, Moderna, BioNTech, Janssen, Astra Zeneca, and their enablers, withheld and willfully omitted safety and effectiveness information from patients and physicians, and should be immediately indicted for fraud.
10. We declare government and medical agencies must be held accountable."

[368] **ADDED since 2/8/2022**

Open Letter To Atagi, TGA and Federal Health Department: Withdraw the experimental gene-based treatment to the general public and especially children

Covid Medical Network, Australia
March 8, 2022
https://www.covidmedicalnetwork.com/open-letters/open-letter-to-atagi.aspx

"The safety signals presented by the data in this letter are of such **grave concern** that the normal decision would be to immediately halt the use of gene-based vaccines to the Australian public. In view of all the data presented,

we request:

That you immediately:

1. Withdraw any information saying these gene-based vaccines are 'safe'
2. Withdraw the gene-based vaccines availability to the general public
3. Absolutely halt the rollout of gene-based vaccines to Australian children as a matter of urgency
4. Provide answers to the questions raised in italics in each section below…

Final Statement: This letter is group signed under the auspices of the Covid Medical Network, Australia – that represents hundreds of clinicians and medical researchers who otherwise feel their careers are at risk if they sign openly. Several contributors to this letter are eminent in their fields. This in itself is an indictment of AHPRA and health employers, who are suppressing valid scientific discourse and the capacity of clinicians to assist their patients make Informed Consent or declination decisions. Others, not under AHPRA's power, have signed openly.

This letter also follows on from numerous letters submitted by medical academics, clinicians and legal practitioners (for example see Annexure W) to Australian politicians and health authorities. In the main those letters have not been responded to, or questions have been superficially addressed or side-stepped. The same has occurred to senators in Questions on Notice. This letter therefore has sought to be comprehensive and has provided direct questions that we request answers to."

[369] **Video (8m): Statement by Professor Christian Perronne at Parliamentary Hearing in Luxemburg**
Christian Perrone, Professor of Infectious and Tropical Diseases at the University of Versailles-St Quentin
January 20, 2022
https://rumble.com/vsyb0y-strong-and-clear-statement-made-by-professor-christian-perronne-with-englis.html

Perrone: "I would have two main messages for you in this crisis: we have flouted science and we have flouted rights.

So, we flouted science, because all the decisions of our politicians were based on experts who unfortunately — we know now, it's public — have major conflicts of interest with the pharmaceutical industry. When they take decisions on the sly, they provide zero scientific references…

And then, these products that we call 'vaccines' — I was considered for years as a vaccine specialist in France, in Europe, in the world.

I believe the biggest scandal of this epidemic is that we have been made to believe that these are vaccines. **They are not at all vaccines** [*emphasis added*].

And we now have the proof that they don't work. That they don't prevent contamination, that they don't prevent severe outcomes…

What shocked me greatly is that the EMA, the European Medicines Agency, admitted, last summer, that **they did not know the full composition** of these 'vaccines' [*emphasis added*]…

And the last word, on rights. I would say that all of it is illegal, since, as it was stated earlier, a conditional use authorization can only be obtained if we have demonstrated that there are no effective treatments. We have hundreds of published studies, the example of India and other countries.

And, above all, the most important is that we are still in Phase 3 experimentation and that by international treaties, including the Nuremberg Code, it is totally forbidden to impose a mandate for an experimental product."

[370] ***Open Letter to the MHRA Regarding Child Death Data: Signals that Covid-19 Vaccines may have caused death in children and young adults***
Health Advisory & Recovery Team (UK)
Dr. Jonathan Engler, et al. (Signatories include 80+ scientists and medical professionals)
January 19, 2022
https://www.hartgroup.org/open-letter-to-the-mhra-regarding-child-death-data/

"Dear Dr Raine, Professor Lim, Mr Javid, Professor Whitty, Sir Patrick Vallance & Dr Harries,

We write to demand an immediate, urgent investigation to determine whether the Covid-19 vaccines are the cause of **significant numbers of deaths** seen recently in male children and young adults [*emphasis added*].

We also request that anonymised data and information known to be available, showing how many children have died following a Covid-19 vaccine and within how many days, be published for full transparency, in the public interest…

In light of the increase in deaths in young males and the known safety concerns, an investigation must be conducted. It is not suggested that the observed increase in mortality proves that the Covid-19 vaccines are causing death, whether via myocarditis or some other mechanism, but a connection cannot be excluded. The potential signal is strong enough that urgent investigations should commence immediately to rule out that possibility. Each recipient of this letter has a duty to investigate. It would be a grave dereliction of duty not to do so."

[371] ***Doctors and scientists urge caution in giving Covid jabs to 'low risk' children***
The Express (UK)
January 8, 2022
https://www.express.co.uk/news/uk/1547050/covid-vaccine-JCVI-omicron-delta-myocarditis

"More than thirty doctors, scientists and MP's have signed a joint letter to the government's vaccine watchdog urging it to 'reassess' the Covid vaccine rollout for healthy 12-15-year-olds following new data showing potentially serious harms of the jab are likely to outweigh any potential benefits…

Letter from politicians and scientists regarding vaccination of children.

To Members of the Joint Committee on Vaccines and Immunisation [*JCVI*],

Re: Review of Child Vaccination Programme…

More data have emerged about the frequency of harmful side effects of Covid vaccination. One study found that for males under 40, risk of myocarditis was up to 14 times higher after vaccination than after infection (101 cases after the Moderna second dose, compared to 7 cases after infection).

It is particularly important to note that the risks of myocarditis in young men and boys seems to increase significantly after a second dose of the vaccine – which is why Chief Medical Officer Professor Chris Whitty initially recommended just one dose be given to 12-15-year-olds – and yet we are now offering second doses to children, despite the evidence of risk growing.

It therefore seems clear that the risk to benefit ratio for child Covid vaccination has worsened since September. The risks of adverse events (including but not limited to myocarditis) increase as more doses are given, and any advantages are reduced as vaccine effectiveness in suppressing Omicron transmission decreases (especially given widespread natural immunity). Given that any potential benefits of vaccinating children were calculated to be marginal at best in the first place, we suspect that this margin has not only evaporated but actually reversed in light of the characteristics of the new and dominant Omicron variant and the increase in robust and durable naturally-acquired immunity…

We believe that the benefit to risk ratio of child vaccination should be reassessed in light of the Omicron variant and new evidence on both vaccine harms and superior natural immunity. We urge the JCVI to review this new evidence and provide updated advice to the Government with regards to the mass vaccination of healthy 12-15-year-olds."

[372] ***7 arguments against compulsory vaccination***
Dr. Jessica Agarwal, Dr. Kai Ambox, *et al*. (Germany)
January 6, 2022
https://7argumente.de/
List of signatories: https://7argumente.de/#autoren

"Dear Members of the German Bundestag,

On the occasion of the debate on the possible introduction of the general vaccination obligation, we have formulated seven scientific arguments which, in our view, prove that there is no reliable scientific basis for compulsory vaccination; From our point of view, this clearly speaks against the introduction of compulsory vaccination…

The 7 arguments ...

The justification for our position is summarized in seven arguments. They are in line with the positions of thousands of scientists in Austria, Switzerland, Italy, France, Scandinavia, Great Britain and the United States…

Argument 2: The risk potential of vaccines is too high

Since the beginning of the vaccination campaign, there has been no systematic research – including the long-term risk potential of the novel vaccines. For the gene-based COVID19 vaccines, it is particularly important that the vaccines and their modes of action are fundamentally new and not researched in long-term studies. Vaccine damage could occur in a different way than the experience with conventional vaccines suggests…

[C]urrent research shows warning signs of a **significant risk potential** of these vaccines [*emphasis added*]:

a) In 2021 and especially in recent months, there has been a significant increase in excess mortality, which has parallels to vaccination…

b) The unusually large increase in cardiovascular and neurological diseases since the start of the vaccination campaign also shows parallels with the vaccination curves…

c) There is evidence that the blood-detectable indicators of the risk of infarction increase significantly after vaccination.

d) The effect of spike proteins on human cell metabolism is largely misunderstood. There is serious evidence that they may be the cause of unwanted side effects.

e) Research results indicate that these side effects may be individual and deviate from the previously known patterns.

f) Current findings on the Omikron variant indicate that people vaccinated against a previous variant are more susceptible to this new variant than non-vaccinated persons."

[373] **ADDED since 2/8/2022**
Video (4m): Statement by Dr. Roger Hodgkinson
December 26, 2021
https://rumble.com/vrforf-dr.-roger-hodkinson-its-all-been-a-pack-of-lies.html

> "I'm Dr. Roger Hodgkinson, a freedom-loving pathologist from Canada. I'm a Fellow of the American College of Pathologists, and the Royal College of Physicians and Surgeons of Canada. My medical degrees are from Cambridge University in the UK, and I've held a number of significant positions, including … President of the Association of Laboratory Physicians of Alberta, President of the Canadian Board of Pathology, CEO of a large community laboratory, and currently I'm the Chairman of an American biotechnology company involved in DNA sequencing.
>
> I have a number of important messages for you resulting from this unprecedented horror show, the worst in medical history. I am viscerally outraged at this totally unnecessary, grotesque human tragedy. So my first message is this: Believe nothing you are being told. It's all been a **pack of lies**, from start to finish, **pure propaganda**…
>
> My second message is that this is a pandemic of fear; fear that was intentionally driven by two major factors – the notorious PCR test and the viciously effective silencing of any counter-narrative…
>
> [M]y third message is simply this, read my lips — Nothing works except effective prophylaxis with Vitamin D and early treatment with Dr. McCullough's protocol."

[374] ***On COVID vaccines: why they cannot work, and irrefutable evidence of their causative role in deaths after vaccination***
Doctors for COVID Ethics symposium
Sucharit Bhakdi and Arne Burkhardt
December 10, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/12/end-covax.pdf
Video version (16m): https://www.bitchute.com/video/fHIT55iM4Zv9/

> "**The evidence**
>
> We herewith present scientific evidence that calls for an **immediate stop** of the use of gene-based COVID-19 vaccines. We first lay out why the agents cannot protect against viral infection. While no positive effects can be expected, we show that the vaccines can trigger self-destructive processes that lead to debilitating illness and death…
>
> **The vaccines can trigger self-destruction**
>
> A natural infection with SARS-CoV-2 (coronavirus) will in most individuals remain localized to the respiratory tract. In contrast, the vaccines cause cells deep inside our body to express the viral spike protein, which they were never meant to do by nature. Any cell which expresses this foreign antigen will come under attack by the immune system, which will involve both IgG antibodies and cytotoxic Tlymphocytes. This may occur in any organ. We are seeing now that the heart is affected in many young people, leading to myocarditis or even sudden cardiac arrest and death. How and why such tragedies might causally be linked to vaccination has remained a matter of conjecture because scientific evidence has been lacking. This situation has now been rectified…

Histopathologic studies: the patients

Histopathologic analyses have been performed on the organs of 15 persons who died after vaccination…

Histopathologic studies: findings

Histopathologic findings of a similar nature were detected in organs of 14 of the 15 deceased. Most frequently afflicted were the heart (14 of 15 cases) and the lung (13 of 15 cases). Pathologic alterations were furthermore observed in the liver (2 cases), thyroid gland (Hashimoto's thyroiditis, 2 cases), salivary glands (Sjögren`s Syndrome; 2 cases) and brain (2 cases).

A number of salient aspects dominated in **all affected tissues of all cases** [*emphasis added*]:

1. inflammatory events in small blood vessels (endothelitis), characterized by an abundance of Tlymphocytes and sequestered, dead endothelial cells within the vessel lumen;
2. the extensive perivascular accumulation of T-lymphocytes;
3. a massive lymphocytic infiltration of surrounding non-lymphatic organs or tissue with Tlymphocytes.

Conclusion

Histopathologic analysis show clear evidence of vaccine-induced autoimmune-like pathology in multiple organs. That myriad adverse events deriving from such auto-attack processes must be expected to very frequently occur in all individuals, particularly following booster injections, is self-evident "

[375] ***Latest statistics on England mortality data suggest systematic miscategorisation of vaccine status and uncertain effectiveness of Covid-19 vaccination***
University of London (UK)
Martin Neil, Norman Fenton, *et al*.
December 3, 2021
https://www.researchgate.net/publication/356756711_Latest_statistics_on_England_mortality_data_suggest_systematic_mis-categorisation_of_vaccine_status_and_uncertain_effectiveness_of_Covid-19_vaccination

"**1. Introduction**

Our recent articles [1, 2] have argued that the simplest and most objective way to assess the overall risk/benefit of Covid-19 vaccines is to compare all-cause mortality rates of the unvaccinated against the vaccinated in each separate age-group. For such an assessment we need accurate periodic data on both age-categorized deaths and the number of vaccinated/unvaccinated people in each age group for that period.

Any systemic errors or biases can lead to conclusions that are inversions of the real situation. For example, simply reporting deaths one week late when a vaccine programme is rolled out will (with statistical certainty) lead to any vaccine, even a placebo, seemingly reducing mortality. The same statistical illusion will happen if any death of a person occurring in the same week as the person is vaccinated is treated as an unvaccinated, rather than vaccinated, death…

In what follows we attempt to analyse this latest 'age stratified' ONS report and other relevant sources of data on mortality to examine patterns of mortality and any connection this might have with vaccination.

In section 2 we examine the all-cause mortality rates in this ONS data. Section 3 then compares vaccinated and unvaccinated non-covid mortality. Section 4 looks at the correlation between the vaccine roll out and non-covid mortality, discussing curious oddities in the data that may be explainable by mis-categorisation of vaccine status at death. In section 5 we look to explain this and correct for this mis-categorisation. Section 6 focuses on covid mortality and looks at the relationship between vaccination and infection and hypothesises that the data is better explained by a temporal offset correction model that takes this into account. Further oddities in the population and death data are revealed in Section 6 and finally Section 7 discusses caveats in the analysis and draws conclusions…

9. Summary and Conclusions…

Whatever the explanations for the observed data, it is clear that it is both unreliable and misleading. We considered the socio-demographic and behavioural differences between vaccinated and unvaccinated that have been proposed as possible explanations for the data anomalies, but found no evidence supports any of these explanations. By Occam's razor we believe the most likely explanations are:

- Systematic miscategorisation of deaths between the different groups of unvaccinated and vaccinated.
- Delayed or non-reporting of vaccinations.
- Systematic underestimation of the proportion of unvaccinated.
- Incorrect population selection for Covid deaths.

With these considerations in mind we applied adjustments to the ONS data and showed that they lead to the conclusion that **the vaccines do not reduce all-cause mortality**, but rather **produce genuine spikes in all-cause mortality shortly after vaccination** [*emphasis added*]."

[376] **Video (15m): *Lt. Col. Theresa Long, MD opinion regarding federal vaccine mandates***
US Congressional statement – Roundtable discussion on COVID-19 vaccines
November 2, 2021
https://rumble.com/von59h-lt.-col.-theresa-long-md-mph-fs.html

"My opinion is formed from my medical education, training, and my first-hand experience treating soldiers injured by the vaccine…

I believe the COVID vaccine is a greater threat to the soldiers' health and military readiness than the virus itself…

In June of 2021, the CDC announced that they were holding an emergency meeting to discuss higher than expected myocarditis in 16-to-24 year olds. Despite this announcement, the military did not even pause their vaccination efforts. Why?

I made numerous efforts to get senior medical leaders to, at the very least, inform soldiers of the risks. Leadership ignored my concerns. This is very troubling for many reasons.

You can't have informed consent if you don't tell your patients of the risks and benefits of a treatment or procedure."

[377] ***Physicians Declaration II***
International Alliance of Physicians and Medical Scientists (Global Covid Summit)
October 29, 2021
https://doctorsandscientistsdeclaration.org/
Note: "as of 8am ET on 1/18/22 over 17,000 doctors & scientists have signed the Rome Declaration"
About: "Global Covid Summit is the product of an international alliance of doctors and scientists, committed to speaking truth to power about Covid pandemic research and treatment. Thousands have died from Covid as a result of being denied life-saving early treatment. The Declaration is a battle cry from physicians who are daily fighting for the right to treat their patients, and the right of patients to receive those treatments - without fear of interference, retribution or censorship by government, pharmacies, pharmaceutical corporations, and big tech. We demand that these groups step aside and honor the sanctity and integrity of the patient-physician relationship, the fundamental maxim 'First Do No Harm', and the freedom of patients and physicians to make informed medical decisions. Lives depend on it."
https://globalcovidsummit.org/page/about

"WE, THE PHYSICIANS OF THE WORLD, united and loyal to the Hippocratic Oath, recognizing the imminent threat to humanity brought forth by current Covid-19 policies, are compelled to declare the following:

WHEREAS, after 20 months of research, millions of patients treated, hundreds of clinical trials performed and scientific data shared, we have demonstrated and documented our success and understanding in combating COVID-19;

WHEREAS, in considering the risks vs. benefits of major policy decisions, thousands of physicians and medical scientists worldwide have reached consensus on three foundational principles;

NOW THEREFORE, IT IS:

RESOLVED, THAT HEALTHY CHILDREN SHALL NOT BE SUBJECT TO FORCED VACCINATION

- Negligible clinical risks from SARS-CoV-2 infection exist for healthy children…
- **Children risk severe, adverse events** from receiving the vaccine…

RESOLVED, THAT NATURALLY IMMUNE PERSONS RECOVERED FROM SARS-CoV-2 SHALL NOT BE SUBJECT TO ANY RESTRICTIONS OR VACCINE MANDATES

- Natural immunity is the **most protective**, and **longest-lasting solution** against the development of COVID-19 disease and its more serious outcomes.
- Naturally immune persons are at the lowest risk of transmission, thus should not be subject to travel, professional, medical or social restrictions.

- Natural immunity provides the best source of herd immunity, a condition necessary for eradicating the Covid virus.

RESOLVED, THAT ALL HEALTH AGENCIES AND INSTITUTIONS SHALL CEASE INTERFERING WITH PHYSICIANS TREATING INDIVIDUAL PATIENTS (view supporting evidence)

- Early intervention with numerous, available agents has proven to be safe and effective, and has **saved hundreds of thousands of lives**.
- No medicine already given regulatory approval shall be restricted from "off-label" use, particularly during this global humanitarian crisis caused by a rapidly mutating virus, which requires quick to adopt treatment strategies.
- Health agencies shall be prohibited from interfering with physicians prescribing evidence-based treatments they deem necessary, and insurance companies must cease blocking payments for life-saving medicine prescribed by doctors.

RECOMMENDED LEGISLATIVE OR EXECUTIVE ACTION:

We believe that **violating any of these three principles unnecessarily** and **directly risks death to our citizens**. We hereby recommend the leaders of states, provinces and nations legislate or take executive action to prohibit the three practices described above [*emphasis added*]."

[378] ***Legal Letter on Behalf of Physicians Regarding Covid-19 Vaccine Injuries (to heads of the DHHS, CDC, and FDA)***
Siri & Glimstad LLP (attorneys)
Aaron Siri and Elizabeth A. Brehm
October 27, 2021
Note: The letter is presented with eleven (11) written statements from physicians detailing their accounts of harms wrought by COVID-19 inoculations, as witnessed in their respective practices.
https://www.sirillp.com/wp-content/uploads/2021/10/Letter-on-Behalf-of-Physicians-Regarding-Covid-19-Vaccine-Injuri-fee0f6941b97b076398c4e8607f573b0.pdf

"We write with the utmost urgency on behalf of physicians from across this country -- see the 11 declarations attached -- whose **firsthand reports of serious and fatal injuries from COVID-19 vaccines** to your public health agencies have not been taken seriously and remain unaddressed [*emphasis added*].

A. Injuries from Covid-19 Vaccines

The harms they have been reporting are not redness at the injection site. The harms are all serious. As detailed in the appended declarations signed by these physicians, they include serious cases of:

small fiber neuropathy; loss of temperature sensation in extremities; constant shakiness to muscles; lesion on spinal cord; paresthesias; tachycardia; fatigue; heat intolerance; gastric paresis; joint pain; subjective fevers; brain fog; tremors; twitching; internal vibrations; tinnitus; blurred vision; dizziness and imbalance; headaches; balance difficulties; burning sensations; menstrual cycle irregularities; hair loss; bladder

incontinence; cognitive impairment; persistent numbness and tingling in hands; constipation; irritability; weakness

Each of these harms has been confirmed, based on the clinical judgment of the patient's treating physician, as being caused by a Covid-19 vaccine.

These physicians and their patients all supported the Covid-19 vaccine. **Almost all of them are fully vaccinated** [*emphasis added*]. It is understandable that you would not want to admit that a product you have authorized, approved, and widely promoted caused harm, but we implore you to have the moral fortitude to rise above your personal interests…

These devastating injuries are detailed in the attached and, as noted, each has been confirmed, based on the clinical judgment of the patient's treating physician, as being caused by a Covid-19 vaccine. It is statistically improbable that any one physician should see numerous serious Covid-19 vaccine injuries if the safety claims regarding this vaccine were true. Yet, in just the appended declarations, there are 4 physicians that have collectively treated more than 18 patients with a serious Covid-19 vaccine injury..."

[379] **Video (65m): Dr. Peter McCullough presentation at 78th Annual Meeting of Association of American Physicians and Surgeons (AAPS)**
AAPS
October 2, 2021
https://odysee.com/@alpha:8/Dr-McCullough-78th-AAPS:d

8:10 mark: "**Clinical Concerns** [*of COVID-19 inoculations*]

- mRNA or adenoviral DNA induce production of the Spike protein
    - Cell, tissue, organ endothelial damage
    - Spike protein circulation (body fluids, donated blood)
- No genotoxicity, teratogenicity, or oncogenicity studies
- Concerning ovarian biodistribution study (Pfizer, Japan)
- Concerning reduced fertility study (Moderna, EMA)
- No EAC [*external advisory committees*], DSMB [*Data and Safety Monitoring Board*], Human Ethics Committee
- No restriction of properly excluded groups from RCTs [random controlled trials]
    - Pregnant women, women of childbearing potential
    - COVID survivors, previously immune
- No effort to restrict vaccination according to risk for COVID-19 hospitalization or death
- No attempts to present or mitigate risks for public"

[380] ***Affidavit of LTC. Theresa Long M.D. in Support of a Motion for a Preliminary Injunction Order***
September 24, 2021
https://www.deepcapture.com/2021/09/affidavit-of-ltc-theresa-long-m-d-in-support-of-a-motion-for-a-preliminary-injunction-order/

"I, Lieutenant Colonel Theresa Long, MD, MPH, FS being duly sworn, depose and state as follows:

1. I make this affidavit, as a whistle blower under the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034, in support of the above referenced MOTION as expert testimony in support thereof…

9. In observing, studying and analyzing all the available data, information, samples, experiences, histories and results of these treatments and inoculations provided, I have formulated a professional opinion, which requires me to report those findings to superiors in the chain of command and colleagues in the military. I have done so with mixed results in terms of acceptance, rejection and threats of punishment for so sharing…

16. **Step 1: Identify the hazards**: As defined by FM 1-02.1 Operational Terms, pg. 1- 48, hazard is a condition with the potential to cause injury, illness, or death of personnel; damage to or loss of equipment or property; or mission degradation.

17. **Step 2: Assess the Hazards**: There are numerous therapeutic agents that have been proven to significantly reduce infection and therefore provide protection from the harmful effects of SARs-CoV-2.

18. Literature has demonstrated that natural immunity is durable, completed, and superior to vaccination immunity to SARs-CoV-2. mRNA vaccines produced by Pfizer and Moderna both have been linked to myocarditis, especially in young males between 16-24 years old,2 The majority of young new Army aviators are in their early twenties. We know there is a risk of myocarditis with each mRNA vaccination. We additionally now know that vaccination does not necessarily prevent infection or transmission of SARs-CoV-2Therefore individuals fully vaccinated with mRNA vaccines have at least two independent risk factors for myocarditis after vaccination. Additional boaster shots add more risk. It is impossible to perform a risk/benefit analysis on the use of mRNA as counter measures to SARs-CoV-2 without further data… Use of mRNA vaccines in our fighting force, presents a risk of undetermined magnitude, in a population in which less than 20 active-duty personnel out of 1.4 million, died of the underlying SARs- CoV-2.…

20. Research shows that most individuals with myocarditis do not have any symptoms. Complications of myocarditis include dilated cardiomyopathy, arrhythmias, sudden cardiac death and carries a mortality rate of 20% at one year and 50% at 5 years…

35. … I am also drawing my own conclusions that will be put into practice in my current role as an Army flight surgeon knowing full well the horrific repercussions this decision may befall me in terms of my career, my relationships and life as an Army doctor.

36. … I find the illnesses, injuries and fatalities [I] observed to be the proximate and causal effect of the Covid 19 vaccinations…

38. I can report of knowing over fifteen military physicians and healthcare providers who have shared experiences of having their safety concerns ignored and being ostracized for expressing or reporting safety concerns as they relate to COVID vaccinations. The politicization of SARs-CoV-2, treatments and vaccination strategies have completely compromised long-standing safety mechanisms, open and honest dialogue, and the trust of our service members in their health system and healthcare providers.

39. The subject matter of this Motion for a Preliminary Injunction and its devastating effects on members of the military compel me to conclude and conduct accordingly as follows:

b) All three of the EUA Covid 19 vaccines (Comirnaty is not available), in the age group and fitness level of my patients, are more risky, harmful and dangerous than having no vaccine at all, whether a person is Covid recovered or facing a Covid 19 infection; …

d) Due to the Spike protein production that is engineered into the user's genome, each such recipient of the Covid 19 Vaccines already has micro clots in their cardiovascular system that present a danger to their health and safety; …

g) That due to the fact that there is no functional myocardial screening currently being conducted, it is my professional opinion that substantial foreseen risks currently exist, which require proper screening of all flight crews; …

k) That, in accordance with the foregoing, I hereby recommend to the Secretary of Defense that all pilots, crew and flight personnel in the military service who required hospitalization from injection or received any Covid 19 vaccination be grounded similarly for further dispositive assessment.

l) That this Court should grant an **immediate injunction to stop the further harm** to all military personnel to protect the health and safety of our active duty, reservists and National Guard troops."

[381] ***The Dangers of Covid-19 Booster Shots and Vaccines: Boosting Blood Clots and Leaky Vessels***
Doctors for COVID Ethics
September 17, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Vaccine-immune-interactions-and-booster-shots_Sep-2021.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"**1. Summary**: … Eminent independent scientists and researchers in the fields of immunology and microbiology have been writing to medical regulators since early 2021, warning of vaccine-related blood clotting and bleeding, including that the official data on blood abnormalities post-vaccination likely represent 'just the tip of a huge iceberg.' Those scientists' warnings pre-dated vaccine suspensions around the world due to acute disease from aberrant blood clotting post-vaccination. The warnings were based on established immunological science, applied to the novel mechanism of action of the gene-based COVID-19 vaccines.

Now, more than six months later, new discoveries in the immunology of SARS-CoV-2 have caught up with the rushed vaccination schedule, confirming and extending the experts' prior warnings. The good news is that we are more comprehensively protected against COVID-19 by our own pre-existing immunity than was previously understood. On the other hand, this

pre-existing immunity aggravates the risk that COVID-19 vaccines will induce blood clotting and/or leaky blood vessels. This risk must be **expected to escalate with each revaccination. Vaccine-induced harm to our blood vessels is unlikely to be rare** [*emphasis added*].

Perhaps the most pertinent finding is that, due to the discovery of a widespread memory-type antibody response to SARS-CoV-2, the antibodies induced by the COVID-19 vaccines can be expected to activate the so-called complement system. This can bring about the destruction of any cell that manufactures the SARS-CoV-2 spike protein, particularly in the circulation. If that happens to the endothelia, that is, the cell layer that lines the inner surfaces of our blood vessels, then those vessels may begin to leak and clots will form. Given that 2021 research showed the spike protein to enter the bloodstream shortly after vaccination, this dangerous endothelial involvement in spike-production is highly likely, and should be expected to occur.

2.1. How and why COVID-19 vaccines incite immunological attack on blood vessel walls. What is wrong with booster shots? … a convergence of evidence from peer reviewed studies published in 2021 reveals that pre-existing immunity to SARS-CoV-2 involves not only T-cells but also memory antibodies, in 99% of people studied… This has profound consequences for the risk-benefit analysis of the vaccines…

2.2. Updated Immune Profile of COVID-19 and its Vaccines: Importantly for COVID-19 vaccination, the 2021 discoveries reveal that the SARS-CoV-2 virus responsible for COVID-19 is not truly new to our immune systems. The finding that the overwhelming majority of people show a memory-type antibody profile to COVID-19 vaccines proves that our immune systems have seen viruses similar to SARS-CoV-2 before. As a result, our bodies have stored an immune memory of that family of viruses, equipping us to fight back more rapidly and powerfully the next time we encounter a similar virus again. As SARS-Cov-2 is of the coronavirus family, this indicates that we possess lasting cross-immunity from previous exposure to other coronaviruses…

2.4. Four Immunological Problems with COVID-19 Vaccines: … While the now clearly established widespread cross-immunity against SARS-CoV-2 implies that most of us are safe from severe COVID-19 disease, it also means that we are vulnerable to the harms of gene-based vaccines. Due to recall immunity against the virus, **vaccination will cause our immune systems to fight aggressively against not only the SARS-CoV-2 spike protein, but against ourselves**. This deleterious autoimmune attack must be expected to intensify with each repeated injection [*emphasis added*]."

[382] ***Open Letter and Notice of Liability from Doctors and Scientists to the EMA and the Members of the European Parliament Regarding COVID-19 Vaccination***
Doctors for COVID Ethics
September 13, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Letter-and-Notice-of-Liability-to-EMA-and-MEPs.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

""This Notice of Liability has been SERVED to you personally.

In March 2021, we alerted you and the world to the fact that the approval of the so-called gene-based COVID-19 vaccines was premature and reckless, and that their administration constituted human experimentation in violation of the Nuremberg Code. Our concerns

regarding the potential dangers of experimental agents were founded on common textbook knowledge of immunobiology and medicine. Simple reasoning led to the foresight that administration of the agents would incur multifaceted pathological events leading, among others, to life-threatening thromboembolic events. You were called upon to suspend the vaccination program until these concerns had been tended to in a satisfactory manner.

This request was scorned and the vaccination program has been rolled out on a global scale, with catastrophic consequences that we trust are known to you…

The current state-of-the-tragedy is summarized in the appended document…

You are hereby placed on notice that you stand to be held personally and individually responsible for causing foreseeable and preventable harm and death from COVID-19 vaccines, and for supporting crimes against humanity, defined as acts that are purposely committed as part of a widespread or systematic policy, directed against civilians, committed in furtherance of state policy…

Importantly, before COVID, this risky gene-based vaccine technology had never before been used on a wide scale against infectious disease and is inherently experimental. The COVID-19 vaccination program is thus **the largest human experiment ever performed in history** [*emphasis added*]."

[383] **ADDED since 2/8/2022**
The Vaccine Death Report
David John Sorenson and Dr. Vladimir Zelenko, MD
September 2021
https://stopworldcontrol.com/downloads/en/vaccines/vaccinereport.pdf

"**Purpose**: The purpose of this report is to document how all over the world millions of people have died, and hundreds of millions of serious adverse events have occurred, after injections with the experimental mRNA gene therapy. We also reveal the real risk of an unprecedented genocide.

Facts: We aim to only present scientific facts and stay away from unfounded claims. The data is clear and verifiable. Over one hundred references can be found for all presented information, which is provided as a starting point for further investigation.

Complicity: The data suggests that we may currently be witnessing the greatest organized mass murder in the history of our world. The severity of this situation compels us to ask this critical question: will we rise to the defense of billions of innocent people? Or will we permit personal profit over justice, and be complicit? Networks of lawyers all over the world are preparing class-action lawsuits to prosecute all who are serving this criminal agenda. To all who have been complicit so far, we say: There is still time to turn and choose the side of truth. Please make the right choice."

[384] ***The Pfizer mRNA vaccine: pharmacokinetics and toxicity***
Doctors for COVID Ethics
Michael Palmer, MD and Sucharit Bhakdi, MD
July 23, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/07/Pfizer-pharmacokinetics-and-toxicity.pdf

"**Abstract**: We summarize the findings of an animal study which Pfizer submitted to the Japanese health authorities in 2020, and which pertained to the distribution and elimination of a model mRNA vaccine. We show that this study clearly presaged grave risks of blood clotting and other adverse effects. The failure to monitor and assess these risks in the subsequent clinical trials, and the grossly negligent review process in conjunction with the emergency use authorizations, have predictably resulted in an unprecedented medical disaster…

Summary: Pfizer's animal data clearly presaged the following risks and dangers:

- blood clotting shortly after vaccination, potentially leading to heart attacks, stroke, and venous thrombosis
- grave harm to female fertility
- grave harm to breastfed infants
- cumulative toxicity after multiple injections

With the exception of female fertility, which can simply not be evaluated within the short period of time for which the vaccines have been in use, all of the above risks have been substantiated since the vaccines have been rolled out—all are manifest in the reports to the various adverse event registries [9]. Those registries also contain a very considerable number of reports on abortions and stillbirths shortly after vaccination, which should have prompted urgent investigation.

We must emphasize again that each of these risks could readily be inferred from the cited limited preclinical data, but were not followed up with appropriate in- depth investigations. In particular, the clinical trials did not monitor any laboratory parameters that could have provided information on these risks, such as those related to blood coagulation (e.g. D-dimers/thrombocytes), muscle cell damage (e.g. troponin/creatine kinase), or liver damage (e.g. γ-glutamyltransferase). That the various regulatory agencies granted emergency use authorization based on such incomplete and insufficient data amounts to nothing less than gross negligence.

Of particularly grave concern is the very slow elimination of the toxic cationic lipids. In persons repeatedly injected with mRNA vaccines containing these lipids—be they directed against COVID, or any other pathogen or disease—this would result in cumulative toxicity. There is a real possibility that cationic lipids will accumulate in the ovaries. The implied grave risk to female fertility demands the most urgent attention of the public and of the health authorities.

Since the so-called clinical trials were carried out with such negligence, the real trials are occurring only now—on a massive scale, and with devastating results. This vaccine, and others, are often called 'experimental.' Calling off this failed experiment is long overdue. Continuing or even mandating the use of this poisonous vaccine, and the apparently imminent issuance of full approval for it are **crimes against humanity**."

[385] **Plaintiffs Motion for Preliminary Injunction: *America's Frontline Doctors, et al., vs. Xavier Becerra, Secretary of the US Department of Health and Human Services***
Lowell H. Becraft, Jr., Thomas Renz, *et al*. (Attorney's for Plaintiffs)
July 19, 2021
https://img1.wsimg.com/blobby/go/3c6a0774-cfad-46fa-aa97-af5aa5e74f00/M%20for%20PI%20file%20stamped.pdf

"**I. Introduction**: Plaintiffs move under Rule 65, Fed.R.Civ.P., for a preliminary injunction against Defendants enjoining them from continuing to authorize the emergency use of the so-called 'Pfizer-BioNTech COVID-19 Vaccine,' 'Moderna COVID-19 Vaccine' and the 'Johnson & Johnson (Janssen) COVID-19 Vaccine' (collectively, the 'Vaccines') pursuant to their respective EUAs, and from granting full Food and Drug Administration ("FDA") approval of the Vaccines.'…

(3) § 360bbb–3(c)(2)(A): The Vaccines Do Not Diagnose, Treat or Prevent SARS-CoV-2 or COVID-19…

In studying the effectiveness of a medical intervention in randomized controlled trials (often called the gold standard of study design), the most useful way to present results is in terms of Absolute Risk Reduction ('ARR'). ARR compares the impact of treatment by comparing the outcomes of the treated group and the untreated group. In other words, if 20 out of 100 untreated individuals had a negative outcome, and 10 out of 100 treated individuals had a negative outcome, the ARR would be 10% (20 - 10 = 10). **According to a study published by the NIH, the ARR for the Pfizer Vaccine is a mere 0.7%, and the ARR for the Moderna Vaccine is only 1.1%**...

(4) § 360bbb–3(c)(2)(B): The Known and Potential Risks of the Vaccine Outweigh their Known and Potential Benefits…

The typical vaccine development process takes between 10 and 15 years, and consists of the following sequential stages: research and discovery (2 to 10 years), pre-clinical animal studies (1 to 5 years), clinical human trials in four phases (typically 5 years). Phase 1 of the clinical human trials consists of healthy individuals and is focused on safety. Phase 2 consists of additional safety and dose-ranging in healthy volunteers, with the addition of a control group. Phase 3 evaluates efficacy, safety and immune response in a larger volunteer group, and requires two sequential randomized controlled trials. Phase 4 is a larger scale investigation into longer- term safety. Vaccine developers must follow this process in order to be able to generate the data the FDA needs in order to assess the safety and effectiveness of a vaccine candidate.

This 10-15 year testing process has been abandoned for purposes of the Vaccines. The first human-to-human transmission of the SARS-CoV-2 virus was not confirmed until January 20, 2020, and less than a year later both mRNA Vaccines had EUAs and for the first time in history this novel mRNA technology was being injected into millions of human beings…

All of the stages of testing have been compressed in time, abbreviated in substance, and are overlapping, which **dramatically increases the risks of the Vaccines** [*emphasis added*]. Plaintiffs' investigation indicates that Moderna and Pfizer designed their Vaccines in only two days. It appears that pharmaceutical companies did not independently verify the genome sequence that China released on January 11, 2020. It appears that the Vaccines were studied

for only 56 days in macaques, and 28 days in mice, and then animal studies were halted. It appears that the pharmaceutical companies discarded their control groups receiving placebos, squandering the opportunity to learn about the rate of long-term complications, how long protection against the disease lasts and how well the Vaccines inhibit transmission. A number of studies were deemed unnecessary and not performed prior to administration in human subjects, including single dose toxicity, toxicokinetic, genotoxicity, carcinogenicity, prenatal and postnatal development, offspring, local tolerance, teratogenic and postnatal toxicity and fertility. The American public has not been properly informed of these dramatic departures from the standard testing process, and the risks they generate.

Plaintiff America's Frontline Doctors' ("AFLDS") medico-legal researchers have analyzed the **accumulated COVID-19 Vaccine risk data**, and report as follows [*emphasis added*]:"

- Migration of the SARS-CoV-2 "Spike Protein" in the Body (p. 11)
- Increased Risk of Death from Vaccines (p. 12)
- Reproductive Health (pp. 12-14)
- Vascular Disease (pp. 14-15)
- Autoimmune Disease (p. 15)
- Neurological Damage (pp. 15-17)
- Effect on the Young (pp. 17-18)
- Chronic Disease (p. 18)
- Antibody Dependent Enhancement (pp. 18-19)
- Vaccine-Driven Disease Enhancement in the Previously Infected (pp. 38-40)
- More Virulent Strains (p. 20)
- Blood Supply (pp. 20-21)"

[386] **Letter to the Chief Executive of the UK Medicines and Healthcare Products Regulatory Agency: *Urgent preliminary report of Yellow Card data up to 26th May 2021***
Evidence-based Medicine Consultancy, Ltd.
Tess Lawrie
June 9, 2021
https://ebmcsquared.org/urgent-preliminary-report-of-yellow-card-data
Note: This link also includes subsequent correspondence between Lawrie and the Chief Executive, Dr. June Raine.

"As the Director of the Evidence-based Medicine Consultancy Ltd and EbMC Squared CiC, I am writing to share with you this urgent preliminary report on the Yellow Card data up to 26th May 2021. Please note that EbMC Squared CiC is a Community Interest Company that conducts research mandated by the public and funded by public donations. We have no conflicts of interest and do not engage in industry-funded work…

We are aware of the limitations of pharmacovigilance data and understand that information on reported Adverse Drug Reactions [*ADR*] should not be interpreted as meaning that the medicine in question generally causes the observed effect or is unsafe to use. We are sharing this preliminary report due to the urgent need to communicate information that should lead to cessation of the vaccination roll out while a full investigation is conducted. According to the recent paper by Seneff and Nigh, potential acute and long-term pathologies include:

- Pathogenic priming, multisystem inflammatory disease and autoimmunity
- Allergic reactions and anaphylaxis
- Antibody dependent enhancement
- Activation of latent viral infections
- Neurodegeneration and prion diseases
- Emergence of novel variants of SARSCoV2
- Integration of the spike protein gene into the human DNA

The nature and variety of ADRs reported to the Yellow Card System are consistent with the potential pathologies described in this paper and supported by other recent scientific papers on vaccine-induced harms, which are mediated through the vaccine spike protein product. It is now apparent that **these products in the blood stream are toxic to humans**. An immediate halt to the vaccination programme is required whilst a full and independent safety analysis is undertaken to investigate the full extent of the harms [*emphasis added*], which the UK Yellow Card data suggest include thromboembolism, multisystem inflammatory disease, immune suppression, autoimmunity and anaphylaxis, as well as Antibody Dependent Enhancement (ADE)."

[387] **ADDED since 2/8/2022**

Why we petitioned the FDA to refrain from fully approving any covid-19 vaccine this year
British Medical Journal — Editorial opinion
Linda Wastila, Peter Doshi, Hamid Merchand, and Kim Witczak
June 8, 2021
https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/

"We are part of a group of clinicians, scientists, and patient advocates who have lodged a formal 'Citizen Petition' with the United States Food and Drug Administration (FDA), asking the agency to delay any consideration of a 'full approval' of a covid-19 vaccine…

[W]e focus on methods and processes, outlining the many remaining unknowns about safety and effectiveness—and suggest the kinds of studies needed to address the open questions…

Our first request is that the FDA require manufacturers to submit data from completed Phase III trials—not interim results. Trials by vaccine manufacturers were designed to follow participants for two years, and should be completed before they are evaluated for full approval, **even if they are now unblinded and lack placebo groups**. These Phase III trials are not simply efficacy studies; they also are necessary and important safety studies (as the study titles say), and all collected data remain invaluable.

We also call on FDA to require a more **thorough assessment of spike proteins** produced *in-situ* by the body following vaccination—**including studies on their full biodistribution, pharmacokinetics, and tissue-specific toxicities**. We ask the FDA to demand manufacturers complete proper biodistribution studies that would be expected of any new drug and request additional studies to better understand the implications of mRNA translation in distant tissues. We call on data demonstrating a **thorough investigation of all serious adverse events reported to pharmacovigilance systems**, carried out by independent, impartial individuals, and for safety data from individuals receiving more than two vaccine doses, in consideration of plans for future booster shots. We ask the FDA to request necessary studies in specific populations, including those previously infected with SARS-CoV-2, pediatric subjects, and those with immunological or other underlying medical complexities. Given the nature of the novel vaccine platforms, our petition asks for experts in gene therapy to be included among the external committee advising the FDA.

These are several of our major requests. The petition has been signed by a group of 27 clinicians, researchers, and consumer advocates with diverse experiences and thoughts about the pandemic. We all agree that there remain many open, unanswered questions surrounding the efficacy and safety of covid-19 vaccines that must be answered before the FDA gives serious consideration to granting full approval."

[388] ***SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers***
Authorea
Roxana Bruno, Peter A. Mccullough, *et al*.
May 2021
https://www.researchgate.net/publication/351670290_SARS-CoV-2_mass_vaccination_Urgent_questions_on_vaccine_safety_that_demand_answers_from_international_health_agencies_regulatory_authorities_governments_and_vaccine_developers

"**Abstract**: … The recently identified role of SARS-CoV-2 Spike glycoprotein for inducing endothelial damage characteristic of COVID-19, even in absence of infection, is extremely relevant given that most of the authorized vaccines induce endogenous production of Spike…

"**Introduction**: … Vaccines for other coronaviruses have never been approved for humans, and data generated in the development of coronavirus vaccines designed to elicit neutralizing antibodies show that they **may worsen COVID-19 disease** via antibody-dependent enhancement (ADE) and Th2 immunopathology, regardless of the vaccine platform and delivery method. Vaccine-driven disease enhancement in animals vaccinated against SARS-CoV and MERS-CoV is known to occur following viral challenge, and has been attributed to immune complexes and Fc-mediated viral capture by macrophages, which augment T-cell activation and inflammation."

Will serious adverse effects from the SARS-CoV-2 vaccines go unnoticed? ... [E]ven in the absence of SARS-CoV-2 virus, Spike glycoprotein alone causes **endothelial damage** and **hypertension** in vitro and in vivo in Syrian hamsters by down-regulating angiotensin-converting enzyme 2 (ACE2) and impairing mitochondrial function [26]. Although these findings need to be confirmed in humans, the implications of this finding are staggering, as all vaccines authorized for emergency use are based on the delivery or induction of Spike

glycoprotein synthesis. In the case of mRNA vaccines and adenovirus-vectorized vaccines, not a single study has examined the duration of Spike production in humans following vaccination. Under the cautionary principle, it is parsimonious to consider vaccine-induced Spike synthesis could cause clinical signs of severe COVID-19, and erroneously be counted as new cases of SARS-CoV-2 infections. If so, the true adverse effects of the current global vaccination strategy may never be recognized unless studies specifically examine this question. There is already non-causal evidence of temporary or sustained increases in COVID-19 deaths following vaccination in some countries (Fig. 1) and in light of Spike's pathogenicity, these deaths must be studied in depth to determine whether they are related to vaccination."

"**Unanticipated adverse reactions to SARS-CoV-2 vaccines**: Another critical issue to consider given the global scale of SARS-CoV-2 vaccination is autoimmunity. SARS-CoV-2 has numerous immunogenic proteins, and all but one of its immunogenic epitopes have similarities to human proteins [27]. These may act as a source of antigens, leading to autoimmunity [28]. While it is true that the same effects could be observed during natural infection with SARS-CoV-2, vaccination is intended for most of the world population, while it is estimated that only 10% of the world population has been infected by SARS-CoV-2, according to Dr. Michael Ryan, head of emergencies at the World Health Organization. **We have been unable to find evidence that any of the currently authorized vaccines screened and excluded homologous immunogenic epitopes** to avoid potential autoimmunity due to pathogenic priming [*emphasis added*]…

At the population level, there could also be vaccine-related impacts. SARS-CoV-2 is a fast-evolving RNA virus that has so far produced more than 40,000 variants some of which affect the antigenic domain of Spike glycoprotein. Given the high mutation rates, vaccine-induced synthesis of high levels of anti-SARS-CoV-2-Spike antibodies could theoretically lead to suboptimal responses against subsequent infections by other variants in vaccinated individuals, a phenomenon known as "original antigenic sin" or antigenic priming. It is unknown to what extent mutations that affect SARS-CoV-2 antigenicity will become fixed during viral evolution, but vaccines could plausibly act as selective forces driving variants with higher infectivity or transmissibility. Considering the high similarity between known SARS-CoV-2 variants, this scenario is unlikely but if future variants were to differ more in key epitopes, the **global vaccination strategy might have helped shape an even more dangerous virus**. This risk has recently been brought to the attention of the WHO as an open letter [*emphasis added*].

Discussion: The risks outlined here are a major obstacle to continuing global SARS-CoV-2 vaccination. Evidence on the safety of all SARS-CoV-2 vaccines is needed before exposing more people to the risk of these experiments, since releasing a candidate vaccine without time to fully understand the resulting impact on health could lead to an exacerbation of the current global crisis."

[389] **ADDED since 2/8/2022**
Video (2m): *Nobel Laureate Luc Montagnier - Warns Covid Vaccine May Lead to 'Neurodegenerative Illness'*
May 27, 2021
https://rumble.com/vhsm3h-nobel-laureate-luc-montagnier-warns-covid-vaccine-may-lead-to-neurodegenera.html

"I am outraged by the fact that we want to vaccinate children, because then we are really affecting a future generation. We need to know, for example, take glyphosate, right? Recent studies on glyphosate have shown that there are epigenetic effects. That means people who eat glyphosate in their diet, pass on something that will affect future generations. Their children, their grand children and great-grand children, they will suffer…

There are epigenetic effects. We need to consider that and not just think of our own generation, but of the future. This messenger RNA that's being injected today in vaccines, may have effects on future generations that are undetected if we arren't searching for them…

It's insanity. It's **vaccination insanity** that I absolutely condemn…

There could be side effects that effect future generations as well, maybe, but most probably in our generation in five to ten years. That's absolutely possible. Notably, something we call neurodegenerative disease."

[390] ***Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19***
International Journal of Vaccine Theory, Practice, and Research
Stephanie Seneff and Greg Nigh
May 10, 2021
https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF~1.PDF

"**Abstract**: Operation Warp Speed brought to market in the United States two mRNA vaccines, produced by Pfizer and Moderna. Interim data suggested high efficacy for both of these vaccines, which helped legitimize Emergency Use Authorization (EUA) by the FDA. However, the exceptionally rapid movement of these vaccines through controlled trials and into mass deployment raises multiple safety concerns. In this review we first describe the technology underlying these vaccines in detail. We then review both components of and the intended biological response to these vaccines, including production of the spike protein itself, and their potential relationship to a wide range of both acute and long-term induced pathologies, such as blood disorders, neurodegenerative diseases and autoimmune diseases. Among these potential induced pathologies, we discuss the relevance of prion-protein-related amino acid sequences within the spike protein. We also present a brief review of studies supporting the potential for spike protein 'shedding', transmission of the protein from a vaccinated to an unvaccinated person, resulting in symptoms induced in the latter. We finish by addressing a common point of debate, namely, whether or not these vaccines could modify the DNA of those receiving the vaccination. While there are no studies demonstrating definitively that this is happening, we provide a plausible scenario, supported by previously established pathways for transformation and transport of genetic material, whereby injected mRNA could ultimately be incorporated into germ cell DNA for transgenerational transmission. We conclude with our recommendations regarding surveillance that will help to clarify the long-term effects of these experimental drugs and allow us to better assess the true risk/benefit ratio of these novel technologies…

mRNA Vaccines, Spike Proteins, and Antibody-Dependent Enhancement (ADE): … In an extended correspondence published in Nature Biotechnology, Eroshenko et al. offer a comprehensive review of evidence suggesting that **ADE could become manifest with any vaccinations employed against SARS-CoV-2** [*emphasis added*]. Importantly, they note that

ADE has been observed with coronavirus vaccines tested in both in vitro and in vivo models (Eroshenko et al., 2020). Others have warned about the same possibility with SARS-CoV-2 vaccines. A theory for how ADE might occur in the case of a SARS-CoV-2 vaccine suggests that non-neutralizing antibodies form immune complexes with viral antigens to provoke excessive secretion of pro-inflammatory cytokines, and, in the extreme case, a cytokine storm causing widespread local tissue damage (Lee et al., 2020). One extensive review of ADE potentially associated with SARS-CoV-2 vaccines noted, "At present, there are no known clinical findings, immunological assays or biomarkers that can differentiate any severe viral infection from immune-enhanced disease, whether by measuring antibodies, T cells or intrinsic host responses" (Arvin et al. 2020; Liu et al.,2019)…

It has been reported that all three US vaccine manufacturers – Moderna, Pfizer, and Johnson & Johnson – are working to develop booster shots (Zaman 2021).With tens of millions of young adults and even children now with vaccine-induced coronavirus spike protein antibodies, there exists the possibility of triggering ADE related to either future SARS-CoV-2 infection or booster injection among this younger population. Time will tell…

Spike Protein Toxicity: … The spike protein generated endogenously by the vaccine could also negatively impact the male testes, as the ACE2 receptor is highly expressed in Leydig cells in the testes (Verma et al., 2020). Several studies have now shown that the **coronavirus spike protein is able to gain access to cells in the testes via the ACE2 receptor,** and **disrupt male reproduction** [*emphasis added*] (Navarra et al., 2020; Wang and Xu, 2020). A paper involving postmortem examination of testicles of six male COVID-19 patients found microscopic evidence of spike protein in interstitial cells in the testes of patients with damaged testicles (Achua et al., 2021)..

Conclusion: Experimental mRNA vaccines have been heralded as having the potential for great benefits, but they also harbor the possibility of potentially tragic and even catastrophic unforeseen consequences. The mRNA vaccines against SARS-CoV-2 have been implemented with great fanfare, but there are many aspects of their widespread utilization that merit concern. We have reviewed some, but not all, of those concerns here, and we want to emphasize that **these concerns are potentially serious** and **might not be evident for years** or even transgenerationally. In order to adequately rule out the adverse potentialities described in this paper, we recommend, at a minimum, that the following research and surveillance practices be adopted:..."

[391] **ADDED since 2/8/2022**
Open Letter: *Letter by NZ Doctors with Concerns Over Pfizer Vaccine*
New Zealand Doctors Speaking Out with Science
April 27, 2021
https://kti.org.nz/?p=361

"We write formally to express our shared concern that:

1. A new prescription only medicine with s23(1) provisional approval, which legally can only be for the treatment of a limited number of patients, is being promoted for the entire adult population of Aotearoa/New Zealand.

2. Medsafe asked 58 questions, but the answers for most of these are not due until March to July 2021.

3. The clinical trials will not be completed until 2023.

4. **Nobody currently knows how safe or effective this novel mRNA technology is in the medium to long term**, but highly credible medical experts around the world, and even some vaccine developers themselves, are predicting problems and raising urgent red-flag concerns…

9. The signatories note that even the promoters of the vaccine do not claim that it prevents transmission and that public representations that the vaccine is effective for this purpose are misleading…

[392] ***Letter to EMA by Professsor Sucharit Bhakdi and colleagues***
Sucharit Bhakdi, Marco Chiesa, Stephen Frost, Margareta Griesz-Brisson, Martin Haditsch, Stefan Hockertz, Lissa Johnson, Ulrike Kämmerer, Michael Palmer, Karina Reiss, Andreas Sönnichsen, and Michael Yeadon
February 28, 2021
https://viruswaarheid.nl/belangrijk/letter-to-ema-28-february-2021/

"As a matter of great urgency, we herewith request that the EMA provide us with responses to the following issues:

1. Following intramuscular injection, it must be expected that **the gene-based vaccines will** reach the bloodstream and **disseminate throughout the body** [1]. We request evidence that this possibility was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

2. If such evidence is not available, it must be expected that the vaccines will remain entrapped in the circulation and be **taken up by endothelial cells**. There is reason to assume that this will happen particularly at sites of slow blood flow, i.e. in small vessels and capillaries [2]. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

3. If such evidence is not available, it must be expected that during expression of the vaccines' nucleic acids, peptides derived from the spike protein will be presented via the MHC I – pathway at the luminal surface of the cells. Many healthy individuals have CD8-lymphocytes that recognize such peptides, which may be due to prior COVID infection, but also to cross-reactions with other types of Coronavirus [3; 4] [5]. We must assume that these lymphocytes will **mount an attack on the respective cells**. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

4. If such evidence is not available, it must be expected that **endothelial damage with subsequent triggering of blood coagulation** via platelet activation will ensue at countless sites throughout the body. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

5. If such evidence is not available, it must be expected that this will lead to a drop in platelet counts, appearance of D-dimers in the blood, and to **myriad ischaemic lesions throughout the body** including in the brain, spinal cord and heart. Bleeding disorders might occur in the

wake of this novel type of DIC-syndrome including, amongst other possibilities, profuse bleedings and haemorrhagic stroke. We request evidence that all these possibilities were excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

6. The SARS-CoV-2 spike protein binds to the ACE2 receptor on platelets, which results in their activation [6]. **Thrombocytopenia** has been reported in severe cases of SARS-CoV-2 infection [7]. Thrombocytopenia has also been reported in vaccinated individuals [8]. We request evidence that the potential danger of platelet activation that would also lead to disseminated intravascular coagulation (DIC) was excluded with all three vaccines prior to their approval for use in humans by the EMA…

Should all such evidence not be available, we demand that approval for use of the gene-based vaccines be withdrawn until all the above issues have been properly addressed by the exercise of due diligence by the EMA [*emphasis original*]."

[393] **ADDED since 2/8/2022**
Video (28m): *30 Doctors/Experts from all over the world warn about COVID vaccine*
December 9, 2020
https://www.bitchute.com/video/7pGPs9KtOBdb/

COVID-19 Natural Immunity and 'Breakthrough' Cases

Natural Immunity

[394] ***#Estimated COVID-19 Burden***
Centers for Disease Control and Prevention (CDC)
Note: This page states 146.6 million 'Estimated Total Infections' in the US as of October 2, 2021.
https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

[395] ***128 Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted***
Brownstone Institute
Paul Elias Alexander, Harvey Risch, Howard Tenenbaum, Ramin Oskoui, Peter McCullough, and Parvez Dara
October 17, 2021
https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

> Provides links to and key excerpts from "128 of the highest-quality, complete, most robust scientific studies and evidence reports/position statements on natural immunity as compared to COVID-19 vaccine-induced immunity."

[396] **ADDED since 2/8/2004**
Video: Anthony Fauci on C-SPAN's Washington Journal
October 11, 2004
https://rumble.com/v1lu0aw-fauci-says-you-dont-need-a-vaccine-if-you-have-natural-immunity.html

> **Host**: "She [a caller] has had the flu for 14 days. Should she get a flue shot?"
>
> **Fauci**: "Well, no. If she got the flue for 14 days, she's as protected as anybody can be because the best vaccination is to get infected yourself. If she really has the flu, she definitely doesn't need a flu vaccine."
>
> **Host**: "She should not get it again?"
>
> **Fauci**: "No, she doesn't need it because the **most potent vaccination is getting infected yourself**."

Note: The citations below are presented in reverse, chronological order.

[397] **ADDED since 2/8/2022**
Past SARS-CoV-2 infection protection against re-infection: a systematic review and meta-analysis
The Lancet — The Lancet COVID-19 Forecasting Team
Caroline Stein, Hasan Nassereldine, *et al*.
February 16, 2023
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)02465-5/fulltext

"**Methods**: In this systematic review and meta-analysis, we identified, reviewed, and extracted from the scientific literature retrospective and prospective cohort studies and test-negative case-control studies published from inception up to Sept 31, 2022, that estimated the reduction in risk of COVID-19 among individuals with a past SARS-CoV-2 infection in comparison to those without a previous infection. We meta-analysed the effectiveness of past infection by outcome (infection, symptomatic disease, and severe disease), variant, and time since infection. We ran a Bayesian meta-regression to estimate the pooled estimates of protection. Risk-of-bias assessment was evaluated using the National Institutes of Health quality-assessment tools. The systematic review was PRISMA compliant and was registered with PROSPERO (number CRD42022303850).

Findings: … Mean pooled effectiveness was greater than 78% against severe disease (hospitalisation and death) for all variants, including omicron BA.1. Protection from re-infection from ancestral, alpha, and delta variants declined over time but remained at 78·6% (49·8–93·6) at 40 weeks. Protection against re-infection by the omicron BA.1 variant declined more rapidly and was estimated at 36·1% (24·4–51·3) at 40 weeks. On the other hand, protection against severe disease remained high for all variants, with **90·2%** (69·7–97·5) for ancestral, alpha, and delta variants, and **88·9%** (84·7–90·9) for omicron BA.1 at 40 weeks."

[398] **ADDED since 2/8/2022**
Duration of immune protection of SARS-CoV-2 natural infection against reinfection
Journal of Medicine — Cornell University and Qatar University
Hiam Chemaitelly, Nico Nagelkerke, *et al*.
September 30, 2022
https://academic.oup.com/jtm/advance-article/doi/10.1093/jtm/taac109/6731972

"**Background**: The future of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic hinges on virus evolution and duration of immune protection of natural infection against reinfection. We investigated the duration of protection afforded by natural infection, the effect of viral immune evasion on duration of protection and protection against severe reinfection, in Qatar, between 28 February 2020 and 5 June 2022…

Results: … **Effectiveness of primary infection against severe, critical or fatal COVID-19 reinfection was 97.3%** (95% CI: 94.9–98.6%), irrespective of the variant of primary infection or reinfection, and with no evidence for waning. Similar results were found in sub-group analyses for those ≥50 years of age."

Conclusions: Protection of natural infection against reinfection wanes and may diminish within a few years. Viral immune evasion accelerates this waning. **Protection against severe reinfection remains very strong**, with no evidence for waning, irrespective of variant, **for over 14 months after primary infection**.

[399] **ADDED since 2/8/2022**

Self-Selected COVID-19 "Unvaccinated" Cohort Reports Favorable Health Outcomes and Unjustified Discrimination in Global Survey

International Journal of Vaccine Theory, Practice, and Research
Robert Verkerk, Christof Plothe, Naseeba Kathrada, and Katarina Lindley
August 12, 2022
https://www.ijvtpr.com/index.php/IJVTPR/article/view/43/125

"**Abstract**: Self-reported data collected independently by the UK-based Control Group Cooperative between September 2021 and February 2022, inclusive,from a self-selected international COVID-19 'unvaccinated' population are discussed. Data come from a cohort of 18,497 participants who provided questionnaire responses monthly. The largest numbers are from Europe, North America, and Australasia. Data were skewed towards the 40-69y age range and included 60% female respondents. Reasons for avoiding COVID-19 'vaccines' were: a preference for natural medicine, distrust of pharma, distrust of government information, poor/limited trial data, and fear of long-term adverse reactions. During the survey period, the greatest incidence of COVID-19 disease was reported in the 50-69y range, peaking at 12.3%, in January 2022. Persons at 70y and above were least affected (1.3%), with 10.7% and 3.8% in the 20 to 49y band, and in the 1 to 19y group, respectively. Most rated their symptoms as 'mild' (14.4%), with **2%** reporting "severe" disease. Fatigue, cough, muscle/body aches, and fever were the four most common. Just **0.4%** of the cohort reported hospitalization (as in-or out-patients). Nearly two-thirds reported taking vitamin D, C, zinc, quercetin, or a combination, for prevention, with 71% using vitamin D, C, and zinc for treatment. Nearly 45% reported 'moderate' to 'severe' mental health issues (depression) during the survey period. Menstrual abnormalities were reported by 36% of women in the 20-49y age band. Reported job losses were greatest in Australia and New Zealand at 29%, followed by 13% in North America. Between 20% and 50% reported being personal targets of hate because of their vaccination status. Between 57% and 61% of respondents in Southern Europe and Western Europe, Australia/New Zealand and South America, reported being targets of governmental victimization. The cohort may not be representative of wider populations given its reliance on self-care. The findings suggest that opting out of the world's largest medical experiment, relying on natural immunity, self-care with supplements, and/or ivermectin or hydroxychloroquine, appeared to contribute to **low incidences** of severe disease, hospitalization, or death. The results imply the urgent need for prospective studies of 'unvaccinated', 'partially vaccinated', and 'fully vaccinated' persons investigating long-term outcomes, behaviors, choices, and discriminatory responses by the state, institutions, or employers based on 'vaccination' status. Public dialogue about the touted 'safety and effectiveness' of vaccines, contrasted with strategies to enhance immune resilience, all in the context of authoritarianism versus autonomy, self-care, personal responsibility, and freedom of choice is needed.

[400] **ADDED since 2/8/2022**

Risk of severe COVID-19 infection among adults with prior exposure to children

Proceedings of the National Academy of Sciences — Kaiser Permanente Northern California

Mathew D. Solomon, Gabrial J. Escobar, *et al*.

July 27, 2022

https://www.pnas.org/doi/full/10.1073/pnas.2204141119

"**Significance**: Epidemiologic data consistently show strong protection for young children against severe COVID-19 illness. Several mechanisms have been proposed to explain this phenomenon, including cross-reactive immunity—in which prior exposure to non-SARS-CoV-2 coronaviruses that commonly infect children confers some resistance to severe COVID-19 illness. We identified 3,126,427 adults (24% [N = 743,814] with children ≤18, and 8.8% [N = 274,316] with youngest child 0–5 years) to assess whether parents of young children–who have high exposure to non-SARS-CoV-2 coronaviruses—may also benefit from potential cross-immunity. In a large, real-world population, exposure to young children was **strongly associated with less severe COVID-19 illness**, after balancing known COVID-19 risk factors. This epidemiologic signal suggests endemic coronavirus cross-immunity may play a role in protection against severe COVID-19 outcomes…

Discussion: We sought to determine whether adults who are at higher likelihood of having prior exposure to non-SARS-CoV-2 coronaviruses may be at decreased risk for severe COVID-19 illness compared to patients at otherwise similar risk of adverse COVID-19 outcomes. To do this, we examined a propensity-matched cohort of patients with prepandemic exposure to young children, a group with the highest rate of upper respiratory infections and the highest likelihood of passing them on to adults (12, 13, 16–18, 27, 28), and compared their rates of COVID-19 infection and rates of severe COVID-19 illness including hospitalization and need for ICU, to adults who did not have the same presumed level of exposure to small children and, by proxy, non-SARS-CoV-2 coronavirus infections. We found that exposure to young children was not associated with a reduction in COVID-19 infection rates, but was associated with protection against severe COVID-19 illness. Those without identifiable household exposure to children based on health insurance enrollment had a **27% higher rate of COVID-19 hospitalization** and a **49% higher rate of COVID-19 hospitalization requiring ICU admission** than those with young children, when calculating outcomes for severe illness relative to the total population within each subgroup. When severe COVID-19 outcomes were calculated as a proportion of those who contracted COVID-19 infection within each age and exposure group—in other words, the risk of a severe adverse COVID-19 outcome among adults with confirmed COVID-19—the findings were more dramatic, with a **49% higher rate of COVID-19 hospitalization** and a **76% higher rate of COVID-19 hospitalization** requiring ICU admission among those without exposure to young children. Our findings, based on data prior to the availability of COVID-19 vaccines, provide potential epidemiologic evidence to suggest the possibility that cross-immunity to non-SARS-CoV-2 coronaviruses may provide a level of protection against severe COVID-19 illness."

[401] **ADDED since 2/8/2022**

Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections

New England Journal of Medicine

Heba N. Altarawneh, Hiam Chemaitelly, *et al*.

July 7, 2022

https://www.nejm.org/doi/full/10.1056/NEJMoa2203965

> "**Methods**: We conducted a national, matched, test-negative, case–control study in Qatar from December 23, 2021, through February 21, 2022, to evaluate the effectiveness of vaccination with BNT162b2 (Pfizer–BioNTech) or mRNA-1273 (Moderna), natural immunity due to previous infection with variants other than omicron, and hybrid immunity (previous infection and vaccination) against symptomatic omicron infection and against severe, critical, or fatal coronavirus disease 2019 (Covid-19).
>
> **Conclusions**: **No discernable differences** in protection against symptomatic BA.1 and BA.2 infection were seen with previous infection, vaccination, and hybrid immunity."

[402] **ADDED since 2/8/2022**

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study

Clinical Infectious Diseases — Maccabi Healthcare Services, Israel

April 5, 2022

https://academic.oup.com/cid/article/75/1/e545/6563799

> "**Methods**: A retrospective observational study of 124 500 persons, compared 2 groups: (1) SARS-CoV-2-naive individuals who received a 2-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine, and (2) previously infected individuals who have not been vaccinated…
>
> **Results**: SARS-CoV-2-naive vaccinees had a **13.06-fold** (95% confidence interval [CI], 8.08–21.11) **increased risk for breakthrough infection** with the Delta variant compared to unvaccinated-previously-infected individuals, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant for symptomatic disease as well. When allowing the infection to occur at any time between March 2020 and February 2021, evidence of waning naturally acquired immunity was demonstrated, although SARS-CoV-2 naive vaccinees still had a 5.96-fold (95% CI: 4.85–7.33) increased risk for breakthrough infection and a 7.13-fold (95% CI: 5.51–9.21) increased risk for symptomatic disease."

[403] ***Prevalence and Durability of SARS-CoV-2 Antibodies Among Unvaccinated US Adults by History of COVID-19***

Journal of the American Medical Association (JAMA)

Jennifer L. Alejo, Jonathan Mitchell, *et al*. (Johns Hopkins University School of Medicine)

February 3, 2022

https://jamanetwork.com/journals/jama/fullarticle/2788894

> "We characterized natural immunity and long-term durability among unvaccinated individuals using anti–spike antibodies, the first line of defense against SARS-CoV-2…

Discussion: In this cross-sectional study of unvaccinated US adults, antibodies were detected in 99% of individuals who reported a positive COVID-19 test result, in 55% who believed they had COVID-19 but were never tested, and in 11% who believed they had never had COVID-19 infection. Anti-RBD levels were observed after a positive COVID-19 test result **up to 20 months**, extending previous 6-month durability data [*emphasis added*]."

[404] **ADDED since 2/8/2022**

The CDC is finally recognizing 'natural immunity' — legislators should follow suit

The Hill

Jeffrey Klausner and Noah Kojima

February 2, 2022

https://thehill.com/opinion/healthcare/592457-the-cdc-is-finally-recognizing-natural-immunity-legislators-should-follow/

"During the delta wave of COVID-19, the incidence of SARS-CoV-2 infection among those with 'enhanced' immunity due to both vaccination and prior infection, was 32.5-fold lower in California and 19.8-fold lower in New York, whereas **rates among those vaccinated alone** (without prior COVID-19) were only 6.2-fold lower in California and 4.5-fold lower in New York. **The rates among those with natural immunity** were 29.0-fold lower in California and 14.7-fold lower in New York. The authors note that hospitalization rates followed a similar pattern.

The report finally acknowledges what many have suspected for a long time — that surviving COVID-19 provides excellent natural immunity not only repeat infection but also to hospitalization and death for the delta variant of COVID-19."

[405] ***COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May–November 2021***

Centers for Disease Control and Prevention

Tomas M. Leon, Vajeera Dorabawila, *et al.*

January 19, 2022

https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm

"**What is added by this report?** During May–November 2021, case and hospitalization rates were highest among persons who were unvaccinated without a previous diagnosis. Before Delta became the predominant variant in June, case rates were higher among persons who survived a previous infection than persons who were vaccinated alone. By early October, persons who survived a previous infection had **lower case rates** than persons who were vaccinated alone [*emphasis added*].

To examine the impact of primary COVID-19 vaccination and previous SARS-CoV-2 infection on COVID-19 incidence and hospitalization rates, statewide testing, surveillance, and COVID-19 immunization data from California and New York (which account for 18% of the U.S. population) were analyzed… Importantly, infection-derived protection was higher after the Delta variant became predominant, a time when vaccine-induced immunity for many persons declined because of immune evasion and immunologic waning."

[406] ***Children develop robust and sustained cross-reactive spike-specific immune responses to SARS-CoV-2 infection***
Nature Immunology
Alexander C. Dowell, Megan S. Butler, *et al*.
December 22, 2021
https://www.nature.com/articles/s41590-021-01089-8

> "**Abstract**: SARS-CoV-2 infection is generally mild or asymptomatic in children but a biological basis for this outcome is unclear. Here we compare antibody and cellular immunity in children (aged 3–11 years) and adults. Antibody responses against spike protein were high in children and seroconversion boosted responses against seasonal Beta-coronaviruses through cross-recognition of the S2 domain. Neutralization of viral variants was comparable between children and adults. Spike-specific T cell responses were more than twice as high in children and were also detected in many seronegative children, indicating pre-existing cross-reactive responses to seasonal coronaviruses. Importantly, children retained antibody and cellular responses 6 months after infection, whereas relative waning occurred in adults. Spike-specific responses were also broadly stable beyond 12 months. Therefore, **children generate robust, cross-reactive and sustained immune responses to SARS-CoV-2** with focused specificity for the spike protein [*emphasis added*]."

[407] **Letter to the Editor: *Severity of SARS-CoV-2 Reinfections as Compared with Primary Infections***
New England Journal of Medicine (Weill Cornell Medicine and Ministry of Public Health, Qatar)
Laith J. Abu-Raddad, Hiam Chemaitelly, and Roberto Bertollini
November 24, 2021
https://www.nejm.org/doi/full/10.1056/NEJMc2108120

> "Using national, federated databases that have captured all SARS-CoV-2–related data since the onset of the pandemic (Section S1 in the Supplementary Appendix, available with the full text of this letter at NEJM.org), we investigated the risk of severe disease (leading to acute care hospitalization), critical disease (leading to hospitalization in an intensive care unit [ICU]), and fatal disease caused by reinfections as compared with primary infections in the national cohort of 353,326 persons with polymerase-chain-reaction (PCR)–confirmed infection between February 28, 2020, and April 28, 2021, after exclusion of 87,547 persons with a vaccination record…
>
> Of 1304 identified reinfections… [t]he odds of severe disease at reinfection were 0.12 times (95% confidence interval [CI], 0.03 to 0.31) that at primary infection (Table 1). There were **no cases of critical disease at reinfection** and 28 cases at primary infection (Table S3), for an odds ratio of 0.00 (95% CI, 0.00 to 0.64). There were **no cases of death from Covid-19 at reinfection** and 7 cases at primary infection, resulting in an odds ratio of 0.00 (95% CI, 0.00 to 2.57). The odds of the composite outcome of severe, critical, or fatal disease at reinfection were 0.10 times (95% CI, 0.03 to 0.25) that at primary infection [*emphasis added*]…
>
> Reinfections had 90% lower odds of resulting in hospitalization or death than primary infections."

[408] ***Immunity to COVID-19 in India through vaccination and natural infection***
Indian Institute of Chemical Biology (India) and University of California, San Diego
Tresa Rani Sarraf, Shreyasi Maity, *et al*.
November 8, 2021
https://www.medrxiv.org/content/10.1101/2021.11.08.21266055v1

"**Abstract**: … In this study we examined correlates of immune protection (humoral and cell mediated) induced by the two vaccines Covishield and Covaxin, in individuals living in and around Kolkata, India. Additionally, we compared the vaccination induced immune response profile with that of natural infection, evaluating thereby if individuals infected during the first wave retained virus specific immunity. Our results indicate that while Covaxin generates better cell-mediated immunity toward the Delta variant of SARS-CoV-2 than Covishield, Covishield is more effective than Covaxin in inducing humoral immunity. Both Covishield and Covaxin, however, are more effective toward the wild type virus [*the strain of original COVID-19*] than the Delta variant. Moreover, **the overall immune response resulting from natural infection** in and around Kolkata is not only to a certain degree better than that generated by vaccination, especially in the case of the Delta variant, but **cell mediated immunity to SARS-CoV-2 also lasts for at least ten months** after the viral infection [*emphasis added*]."

[409] ***Protective immunity after recovery from SARS-CoV-2 infection***
Infectious Diseases – The Lancet
Noah Kojima and Jeffrey D. Klausner
November 8, 2021
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00676-9/fulltext

"We reviewed studies published in PubMed from inception to Sept 28, 2021, and found well conducted biological studies showing protective immunity after infection (panel). Furthermore, multiple epidemiological and clinical studies, including studies during the recent period of predominantly delta (B.1.617.2) variant transmission, found that the risk of repeat SARS-CoV-2 infection decreased by 80.5–100% among those who had had COVID-19 previously (panel). The reported studies were large and conducted throughout the world. Another laboratory-based study that analysed the test results of 9119 people with previous COVID-19 from Dec 1, 2019, to Nov 13, 2020, found that only 0.7% became reinfected. In a study conducted at the Cleveland Clinic in Cleveland, OH, USA, those who had not previously been infected had a COVID-19 incidence rate of 4.3 per 100 people, whereas **those who had previously been infected had a COVID-19 incidence rate of 0 per 100 people** [*emphasis added*]. Furthermore, a study conducted in Austria found that the frequency of hospitalisation due to a repeated infection was five per 14,840 (0·03%) people and the frequency of death due to a repeated infection was one per 14,840 (0·01%) people… Due to the strong association and biological basis for protection, clinicians should consider counselling recovered patients on their risk for reinfection and document previous infection status in medical records.

[T]hose studies show that **protection from reinfection is strong** and **persists for more than 10 months** of follow-up [*emphasis added*], it is unknown how long protective immunity will truly last. Many systemic viral infections, such as measles, confer long-term, if not lifelong, immunity, whereas others, such as influenza, do not (due to changes in viral genetics). We are limited by the length of current reported follow-up data to know with certainty the expected duration that previous infection will protect against COVID-19. Encouragingly, authors of a study conducted among recovered individuals who had experienced mild SARS-CoV-2

infection reported that mild infection induced a robust antigen-specific, long-lived humoral immune memory in humans…

Some people who have recovered from COVID-19 might not benefit from COVID-19 vaccination. In fact, one study found that previous COVID-19 was **associated with increased adverse events** following vaccination with the Comirnaty BNT162b2 mRNA vaccine (Pfizer–BioNTech) [*emphasis added*]…

Given the evidence of immunity from previous SARS-CoV-2 infection, however, policy makers should consider recovery from previous SARS-CoV-2 infection equal to immunity from vaccination for purposes related to entry to public events, businesses, and the workplace, or travel requirements."

[410] **CDC response to Freedom of Information Act Request re. COVID-19 Reinfection and Transmission**
Submitted by Siri & Glimstad LLP (attorneys) to Centers for Disease Control and Prevention (CDC)
November 5, 2021
https://www.sirillp.com/wp-content/uploads/2021/11/21-02152-Final-Response-Letter-Brehm-1.pdf

"Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your September 02, 2021, Freedom of Information Act (FOIA) request on September 02, 2021, seeking:

> 'Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected.'

A search of our records failed to reveal any documents pertaining to your request. The CDC Emergency Operations Center (EOC) conveyed that **this information is not collected** [*emphasis added*]…

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer"

[411] **Video (6m): Testimony of Dr. Aditi Bhargava**
November 3, 2021
https://odysee.com/@Anon:96/aditibhargava:f

Bhargava: "My name is Aditi Bhargava and I'm a professor at UCSF and a microbiologist with 33 years of research experience. These are my scientific views…

Natural immunity is the gold standard.

CDC estimates that nearly 43% of the country has already been infected with SARS-CoV-2 and thus naturally immune. And that was all before the more transmissible delta variant took hold.

Living in a bubble of sterile conditions is counterproductive to everything we know about strengthening the immune system. It's Immunology 101. To downplay the beneficial and protective powers of our immune system goes against the founding principles of immunology. Several studies about SARS-CoV-2 are validating that knowledge.

There is **no documented case of a naturally immune person getting re-infected with severe disease or hospitalisation**, despite the first case reported nearly two years ago. In sharp contrast, **there are thousands of cases of severe COVID hospitalisations and deaths in fully vaccinated people** [*emphasis added*].

CDC now estimates 90% of Americans over the age of 16 have antibodies against SARS-CoV-2. But vaccine induced antibodies are only a small fraction of our immune responses.

Immune studies from the British Health Ministry suggests that Covid vaccines might interfere with the ability of our immune system to produce antibodies against other parts of the virus, [a] crucial aspect for developing cross protection. The spike antibodies are incomplete and cherry-picked stories.

Vaccine induced protection fell through **33 to 42% within 3 months** [*emphasis added*]. That is no different than the protection the unvaccinated have. Hence mandates to prevent spread by using spike antibody levels as the gold standard is gross misrepresentation of data."

[412] ***A Review and Autopsy of Two COVID Immunity Studies***
Brownstone Institute
Martin Kulldorff
November 2, 2021
https://brownstone.org/articles/a-review-and-autopsy-of-two-covid-immunity-studies/

"How effective is immunity after Covid recovery relative to vaccination? An Israeli study by Gazit et al. found that the vaccinated have a 27 times higher risk of symptomatic infection than the Covid recovered. At the same time, the vaccinated were nine times more likely to be hospitalized for Covid. In contrast, a CDC study by Bozio et al. claims that the Covid recovered are five times more likely to be hospitalized for Covid than the vaccinated. Both studies cannot be right.

I have worked on vaccine epidemiology since I joined the Harvard faculty almost two decades ago as a biostatistician. I have never before seen such a large discrepancy between studies that are supposed to answer the same question. In this article, I carefully dissect both studies, describe how the analyses differ, and explain why the Israeli study is more reliable…

Conclusion: … Based on the solid evidence from the Israeli study, the Covid recovered have stronger and longer-lasting immunity against Covid disease than the vaccinated. Hence, there is no reason to prevent them from activities that are permitted to the vaccinated. In fact, it is discriminatory."

[413] ***One-year sustained cellular and humoral immunities of COVID-19 convalescents***
Clinical Infectious Diseases
Jie Zhang, Hao Lin, *et al*.
October 5, 2021
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab884/6381561

"**Results**: SARS-CoV-2-specific IgG antibodies, and also NAb can persist among over 95% COVID-19 convalescents from 6 months to 12 months after disease onset."

[414] ***Persistence of neutralizing antibodies a year after SARS-CoV-2 infection in humans***
European Journal of Immunology
Anu Haveri, Nina Ekstron, *et al*.
September 27, 2021
https://onlinelibrary.wiley.com/doi/10.1002/eji.202149535

"**Abstract**: Most subjects develop antibodies to SARS-CoV-2 following infection. In order to estimate the duration of immunity induced by SARS-CoV-2 it is important to understand for how long antibodies persist after infection in humans. Here, we assessed the persistence of serum antibodies following wild-type SARS-CoV-2 infection at 8 and 13 months after diagnosis in 367 individuals… We found that **NAb [*neutralizing antibodies*] against the wild-type virus persisted in 89%** and S-IgG in 97% **of subjects for at least 13 months** after infection [*emphasis added*]."

[415] **ADDED since 2/8/2022**
FAQ about COVID-19
Public Health Agency of Sweden
September 17, 2021
https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/covid-19/covid-19-faq/

"**Can you get COVID-19 more than once?**

If you have had COVID-19, you have some protection against reinfection. This means that you are less likely to become infected and seriously ill, and less likely to infect others if you are exposed to the virus again. Over time, the protection that you get after an infection wanes and there is an increased risk of getting infected again. At present, we estimate that the protection after having had COVID-19 lasts **at least six months** from the time of infection."

[416] ***The prevalence of adaptive immunity to COVID-19 and reinfection after recovery – a comprehensive systematic review and meta-analysis of 12,011,447 individuals***
Qatar University
Tawanda Chivese, Joshua T. Matizanadzo, *et al*.
September 17, 2021
https://www.medrxiv.org/content/10.1101/2021.09.03.21263103v3.full-text

"**Methods and analyses**: A synthesis of existing research was conducted. The Cochrane Library for COVID-19 resources, the China Academic Journals Full Text Database, PubMed, and Scopus as well as preprint servers were searched for studies conducted between 1 January 2020 to 1 April 2021. We included studies with the relevant outcomes of interest. All included studies were assessed for methodological quality and pooled estimates of relevant

outcomes were obtained in a meta-analysis using a bias adjusted synthesis method…

Results: Fifty-four studies, from 18 countries, with a total of 12 011 447 individuals, followed up to 8 months after recovery, were included. At 6-8 months after recovery, the **prevalence of detectable SARS-CoV-2 specific immunological memory remained high**; IgG – 90.4% …, CD4+ - 91.7%..., and memory B cells 80.6%... and the **pooled prevalence of reinfection was 0.2%** [*emphasis added*]. Individuals who recovered from COVID-19 had an 81% reduction in odds of a reinfection.

Conclusion: Around 90% of people previously infected with SARS-CoV-2 had evidence of immunological memory to SARS-CoV-2, which was sustained for at least 6-8 months after recovery, and had a low risk of reinfection."

[417] ***Vaccinating people who have had covid-19: why doesn't natural immunity count in the US?***
British Medical Journal
Jennifer Block
September 13, 2021
https://www.bmj.com/content/374/bmj.n2101

"The US CDC estimates that SARS-CoV-2 has infected more than 100 million Americans, and evidence is mounting that natural immunity is at least as protective as vaccination. Yet public health leadership says everyone needs the vaccine…

The evidence: 'Starting from back in November, we've had a lot of really important studies that showed us that memory B cells and memory T cells were forming in response to natural infection,' says Gandhi [*an infectious disease specialist at University of California San Francisco*]. Studies are also showing, she says, that these memory cells will respond by producing antibodies to the variants at hand.

Gandhi included a list of some 20 references on natural immunity to covid in a long Twitter thread supporting the durability of both vaccine and infection induced immunity. 'I stopped adding papers to it in December because it was getting so long,' she tells The BMJ.

But the studies kept coming. A National Institutes of Health (NIH) funded study from La Jolla Institute for Immunology found 'durable immune responses' in 95% of the 200 participants up to eight months after infection. One of the largest studies to date, published in Science in February 2021, found that although antibodies declined over 8 months, memory B cells increased over time, and the half life of memory CD8+ and CD4+ T cells suggests a steady presence.

Real world data have also been supportive. Several studies (in Qatar, England, Israel, and the US) have found infection rates at equally low levels among people who are fully vaccinated and those who have previously had covid-19. Cleveland Clinic surveyed its more than 50 000 employees to compare four groups based on history of SARS-CoV-2 infection and vaccination status. Not one of over 1300 unvaccinated employees who had been previously infected tested positive during the five months of the study. Researchers concluded that that cohort 'are unlikely to benefit from covid-19 vaccination.' In Israel, researchers accessed a database of the entire population to compare the efficacy of vaccination with previous infection and found nearly identical numbers. 'Our results question the need to vaccinate previously infected individuals,' they concluded' …

Different risk-benefit analysis? … A large study in the UK and another that surveyed people internationally found that people with a history of SARS-CoV-2 infection experienced greater rates of side effects after vaccination. Among 2000 people who completed an online survey after vaccination, those with a history of covid-19 were **56% more likely to experience a severe side effect that required hospital care** [*emphasis added*].

Patrick Whelan, of UCLA, says the 'sky high' antibodies after vaccination in people who were previously infected may have contributed to these systemic side effects. 'Most people who were previously ill with covid-19 have antibodies against the spike protein. If they are subsequently vaccinated, those antibodies and the products of the vaccine can form what are called immune complexes,' he explains, which may get deposited in places like the joints, meninges, and even kidneys, creating symptoms."

[418] ***Open Letter and Notice of Liability from Doctors and Scientists to the EMA and the Members of the European Parliament Regarding COVID-19 Vaccination***
Doctors for COVID Ethics
September 13, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Letter-and-Notice-of-Liability-to-EMA-and-MEPs.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"Until recently, the immune profile of COVID-19 and COVID-19 vaccines was not fully characterised. While we have known since mid-2020 that robust and lasting memory T-cell immunity to SARS-CoV-2 exists, the antibody picture has been less clear. Now, however, a convergence of evidence from **peer reviewed studies published in 2021** reveals that **pre-existing immunity to SARS-CoV-2 involves not only T-cells but also memory antibodies**, in 99% of people studied [*emphasis added*].

[A] key point to note is that if we inject a live traditional vaccine into a person who is already immune—due to either a previous vaccination, or to prior infection with the corresponding wild-type virus—the extent of cell destruction will be much reduced. Such a person will already have antibodies to the virus; these will recognize the viral protein antigens and will bind and inactivate most of the vaccine virus particles before they manage to infect a cell. Therefore, even though the killer T-cells may be all riled up, they will not find very many infected cells to pounce on.

The crucial difference between a conventional live virus vaccine and a gene-based COVID vaccine—and in particular an mRNA vaccine—is that the latter contains no protein antigens whatsoever; instead, it only contains the blueprint for their synthesis inside the infected cells. Therefore, if such a vaccine is injected into a person with antibodies and existing T-cell immunity, the vaccine particles will 'fly under the radar' of the antibody defence and reach our body cells unimpeded. The cells will then produce the spike protein, and subsequently be destroyed and attacked by the killer T-cells. The antibodies, rather than preventing the carnage, will join in by also binding to the cell-associated spike protein and directing the complement system (see later) and other immune effector mechanisms against these cells. In a nutshell, **pre-existing immunity** mitigates the risk of conventional vaccines, but it **amplifies the risk of gene-based vaccines** [*emphasis added*]."

[419] ***Protracted yet Coordinated Differentiation of Long-Lived SARS-CoV-2-Specific CD8+ T Cells during Convalescence***
Journal of Immunology (University of California, San Franscisco)
Toncui Ma, Heeju Ryu, *et al*.
September 1, 2021
https://www.jimmunol.org/content/207/5/1344

"**Abstract**: … These results suggest that following a typical case of mild COVID-19, SARS-CoV-2–specific CD8+ T cells not only persist but continuously differentiate in a coordinated fashion well into convalescence into a state characteristic of long-lived, self-renewing memory."

[420] ***Anti- SARS-CoV-2 Receptor Binding Domain Antibody Evolution after mRNA Vaccination***
The Rockefeller University (New York)
Alice Cho, Frauke Muecksch, *et al*.
August 30, 2021
https://www.biorxiv.org/content/10.1101/2021.07.29.454333v2.full

"**Summary**: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection produces B-cell responses that continue to evolve for at least one year. During that time, memory B cells express increasingly broad and potent antibodies that are **resistant to mutations found in variants of concern** [*emphasis added]*…"

[421] ***A Systematic Review of the Protective Effect of Prior SARS-CoV-2 Infection on Repeat Infection***
medRxiv
N. Kojima, N.K. Shrestha, and J.D. Klausner
August 29, 2021
https://www.medrxiv.org/content/10.1101/2021.08.27.21262741v1

"**Methods**: For this systematic review, we searched scientific publications on PubMed and, the pre-print server, MedRxiv through August 18, 2021… To identify relevant studies with appropriate control groups, we developed the following criteria for studies to be included in the systematic analysis: (1) baseline polymerase chain reaction (PCR) testing, (2) a negative comparison group, (3) longitudinal follow-up, (4) a cohort of human participants, i.e., not a case report or case series, and (5) outcome determined by PCR. The review was conducted following PRISMA guidelines. We assessed for selection, information, and analysis bias, per PRISMA guidelines.

Results: We identified 1,392 reports. Of those, 10 studies were eligible for our systematic review. The **weighted average risk reduction against reinfection was 90.4%** with a standard deviation of 7.7%. Protection against SARS-CoV-2 reinfection was observed for up to 10 months [*emphasis added*]."

[422] ***Having SARS-CoV-2 once confers much greater immunity than a vaccine—but vaccination remains vital***
Science Insider
Meredity Wadman
August 26, 2021
https://www.science.org/news/2021/08/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-vaccination-remains-vital

> "The natural immune protection that develops after a SARS-CoV-2 infection offers considerably more of a shield against the Delta variant of the pandemic coronavirus than two doses of the Pfizer-BioNTech vaccine, according to a large Israeli study... The newly released data show people who once had a SARS-CoV-2 infection were much less likely than never-infected, vaccinated people to get Delta, develop symptoms from it, or become hospitalized with serious COVID-19…
>
> The new analysis relies on the database of Maccabi Healthcare Services, which enrolls about 2.5 million Israelis. The study, led by Tal Patalon and Sivan Gazit at KSM, the system's research and innovation arm, found in two analyses that never-infected people who were vaccinated in January and February were, in June, July, and the first half of August, six to 13 times more likely to get infected than unvaccinated people who were previously infected with the coronavirus. In one analysis, comparing more than 32,000 people in the health system, the risk of developing symptomatic COVID-19 was **27 times higher** among the vaccinated, and the risk of hospitalization **eight times higher** [*emphasis added*]."

[423] ***Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection***
Tel-Aviv University (Israel)
Ariel Israel, Yotam Shenhar, *et al*.
August 22, 2021
https://www.medrxiv.org/content/10.1101/2021.08.19.21262111v1.full-text

> "**Objective**: To determine the kinetics of SARS-CoV-2 IgG antibodies following administration of two doses of BNT162b2 vaccine, or SARS-CoV-2 infection in unvaccinated individuals.
>
> **Results**: A total of 2,653 individuals fully vaccinated by two doses of vaccine during the study period and 4,361 convalescent patients were included. Higher SARS-CoV-2 IgG antibody titers were observed in vaccinated individuals (median 1581 AU/mL IQR [533.8-5644.6]) after the second vaccination, than in convalescent individuals (median 355.3 AU/mL IQR [141.2-998.7]; p<0.001). In vaccinated subjects, **antibody titers** decreased by up to **40%** each subsequent month while in convalescents they decreased by less than **5%** per month…
>
> **Conclusions**: This study demonstrates individuals who received the Pfizer-BioNTech mRNA vaccine have different kinetics of antibody levels compared to patients who had been infected with the SARS-CoV-2 virus, with higher initial levels but a much faster exponential decrease in the first group."

[424] ***Pre-activated antiviral innate immunity in the upper airways controls early SARS-CoV-2 infection in children***
Nature Biotechnology
J. Loske, J. Rohmel, *et al*.
August 18, 2021
https://www.nature.com/articles/s41587-021-01037-9

"**Abstract**: … Children displayed higher basal expression of relevant pattern recognition receptors such as MDA5 (IFIH1) and RIG-I (DDX58) in upper airway epithelial cells, macrophages and dendritic cells, resulting in stronger innate antiviral responses upon SARS-CoV-2 infection than in adults. We further detected distinct immune cell subpopulations including KLRC1 (NKG2A)+ cytotoxic T cells and a CD8+ T cell population with a memory phenotype occurring predominantly in children. Our study provides evidence that the airway immune cells of children are primed for virus sensing, resulting in a stronger early innate antiviral response to SARS-CoV-2 infection than in adults."

[425] ***Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections***
KSM Research and Innovation Center, Maccabitech Institute for Research and Innovation (Israel)
Sivan Gazit, Roei Shlezinger, *et al*.
August 13, 2021
https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1

"**Results**: SARS-CoV-2-naïve vaccinees [*vaccine recipients with no prior SARS-CoV-2 infection*] had a **13.06-fold** (95% CI, 8.08 to 21.11) **increased risk for breakthrough infection** with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant (P<0.001) for symptomatic disease as well. When allowing the infection to occur at any time before vaccination (from March 2020 to February 2021), evidence of waning natural immunity was demonstrated, though SARS-CoV-2 naïve vaccinees had a **5.96-fold** (95% CI, 4.85 to 7.33) **increased risk for breakthrough infection** and a **7.13-fold** (95% CI, 5.51 to 9.21) **increased risk for symptomatic disease** [*emphasis added*]. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalizations compared to those that were previously infected.

Conclusions: This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity."

[426] ***Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants***
Science magazine
Lingshu Wang, Tongqing Zhou, *et al*.
August 13, 2021
https://science.sciencemag.org/content/373/6556/eabh1766

"**Introduction**: Worldwide appearance of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern (VOCs) with increased transmissibility and resistance to therapeutic antibodies necessitates the discovery of broadly reactive antibodies. We isolated

receptor binding domain (RBD) targeting antibodies that potently neutralize 23 variants…

Conclusion: Our study demonstrates that convalescent subjects previously infected with ancestral variant SARS-CoV-2 produce antibodies that cross-neutralize emerging VOCs with high potency."

[427] ***Seven-month kinetics of SARS-CoV-2 antibodies and role of pre-existing antibodies to human coronaviruses***
Nature Communications
Natalia Ortega, Marta Ribes, *et al*.
August 6, 2021
https://www.nature.com/articles/s41467-021-24979-9

"**Abstract**: Unraveling the long-term kinetics of antibodies to SARS-CoV-2 and the individual characteristics influencing it, including the impact of pre-existing antibodies to human coronaviruses causing common cold (HCoVs), is essential to understand protective immunity to COVID-19 and devise effective surveillance strategies. IgM, IgA and IgG levels against six SARS-CoV-2 antigens and the nucleocapsid antigen of the four HCoV (229E, NL63, OC43 and HKU1) were quantified by Luminex, and antibody neutralization capacity was assessed by flow cytometry, in a cohort of health care workers followed up to 7 months (N = 578). **Seroprevalence increases over time** from 13.5% (month 0) and 15.6% (month 1) to 16.4% (month 6) [*emphasis added*]. Levels of antibodies, including those with neutralizing capacity, are stable over time, except IgG to nucleocapsid antigen and IgM levels that wane. After the peak response, anti-spike antibody levels increase from ~150 days post-symptom onset in all individuals (73% for IgG), in the absence of any evidence of re-exposure. IgG and IgA to HCoV are significantly higher in asymptomatic than symptomatic seropositive individuals. Thus, pre-existing cross-reactive HCoVs antibodies could have a protective effect against SARS-CoV-2 infection and COVID-19 disease."

[428] ***Live virus neutralization testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2***
Emerging Microbes & Infections
Carla Saade, Claudia Gonzalez, *et al*.
August 1, 2021
https://www.tandfonline.com/doi/full/10.1080/22221751.2021.1945423

"SARS-CoV-2 mutations appeared recently and can lead to conformational changes in the spike protein and probably induce modifications in antigenicity. We assessed the neutralizing capacity of antibodies to prevent cell infection, using a live virus neutralization test with different strains [19A (initial one), 20B (B.1.1.241 lineage), 20I/501Y.V1 (B.1.1.7 lineage), and 20H/501Y.V2 (B.1.351 lineage)] in serum samples collected from different populations: two-dose vaccinated COVID-19-naive healthcare workers (HCWs; Pfizer-BioNTech BNT161b2), 6-months post mild COVID-19 HCWs, and critical COVID-19 patients…

As a whole, critical patients exhibited a strong neutralizing response against all the tested strains; despite a slight reduction in NAb titres for both variants by comparison to the wild-type strain, no neutralization escape occurred against the two VOC due to the high titres of NAb...

The 6-month neutralizing response of HCWs with mild COVID-19 was slightly reduced towards both variants by comparison to the wild type strain...

Another striking finding of the present study is the **reduced neutralizing response observed towards the 20H/501Y.V2 variant in fully immunized subjects with the BNT162b2 vaccine** by comparison to the wild type and 20I/501Y.V1 variant. These results are in accordance with that observed for the same vaccine in numerous studies [*emphasis added*] using pseudotype viruses or authentic variant strains..."

[429] ***One Year after Mild COVID-19: The Majority of Patients Maintain Specific Immunity, But One in Four Still Suffer from Long-Term Symptoms***
Journal of Clinical Medicine (University of Augsburg, Germany)
Andreas Rank, Athanasia Tzortzini, *et al*.
July 27, 2021
https://www.mdpi.com/2077-0383/10/15/3305

"**Abstract**: … This study focused on mild COVID-19 and investigated correlations of immunity with persistent symptoms and immune longevity… Activation-induced marker assays identified specific T-helper cells and central memory T-cells in 80% of participants at a 12-month follow-up."

[430] ***Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells***
Cell Reports Medicine
Kristen W. Cohen, Susanne L. Linderman, *et al*.
July 20, 2021
https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(21)00203-2?_return

"**Summary**: Ending the COVID-19 pandemic will require long-lived immunity to SARS-CoV-2. Here, we evaluate 254 COVID-19 patients longitudinally up to eight months and find durable broad-based immune responses… Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients…

Discussion: … Our findings show that most COVID-19 patients induce a wide-ranging immune defense against SARS-CoV-2 infection, encompassing antibodies and memory B cells recognizing both the RBD and other regions of the spike, broadly-specific and polyfunctional CD4+ T cells, and polyfunctional CD8+ T cells. The immune response to natural infection is likely to provide some degree of protective immunity even against SARS-CoV-2 variants because the CD4+ and CD8+ T cell epitopes will likely be conserved."

[431] ***CDC/IDSA COVID-19 Clinician Call***
Centers for Disease Control and Prevention (CDC) and Infectious Diseases Society of America (IDSA)
July 17, 2021
https://www.idsociety.org/globalassets/idsa/media/clinician-call-slides--qa/07-17-21-clinician-call-slides-1.pdf

Slide 1: "70th in a series of weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19"

Slide 39: "Immune responses to SARS-CoV-2 following natural infection can persist for at least 11 months"

[432] ***Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine***
University of California, Irvine
Suhas Sureshchandra, Sloan A. Lewis, et al.
July 15, 2021
https://www.biorxiv.org/content/10.1101/2021.07.14.452381v1.full

"**Abstract**: … We used single-cell RNA sequencing and functional assays to compare humoral and cellular responses to two doses of mRNA vaccine with responses observed in convalescent individuals with asymptomatic disease. Our analyses revealed enrichment of spike-specific B cells, activated CD4 T cells, and robust antigen-specific polyfunctional CD4 T cell responses in all vaccinees. On the other hand, CD8 T cell responses were both weak and variable… Natural infection induced expansion of larger CD8 T cell clones occupied distinct clusters, likely due to the recognition of a broader set of viral epitopes presented by the virus not seen in the mRNA vaccine."

[433] ***Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees***
Curative, Inc.
N Kojima, A Roshani, M Brobeck, A Baca, and JD Klausner
July 8, 2021
https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2.full-text

"**Introduction**: … Among a clinical laboratory that has been conducting routine workforce screening since the beginning of the pandemic, we aimed to assess the relative risk of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) infection among individuals who were SARS-CoV-2 naïve, previously infected, or vaccinated…

Conclusion: Previous SARS-CoV-2 infection and vaccination for SARS-CoV-2 were associated with decreased risk for infection or re-infection with SARS-CoV-2 in a routinely screened workforce. There was **no difference in the infection incidence** between vaccinated individuals and individuals with previous infection [*emphasis added*]."

[434] ***Temporal maturation of neutralizing antibodies in COVID-19 convalescent individuals improves potency and breadth to circulating SARS-CoV-2 variants***
Immunity (National Institute of Infectious Diseases, Tokyo, Japan)
Saya Moriyama, Yu Adachi, *et al*.
July 2, 2021
https://www.cell.com/immunity/fulltext/S1074-7613(21)00259-4

"**Summary**: Antibody titers against SARS-CoV-2 slowly wane over time. Here, we examined how time affects antibody potency. To assess the impact of antibody maturation on durable neutralizing activity against original SARS-CoV-2 and emerging variants of concern (VOCs), we analyzed receptor binding domain (RBD)-specific IgG antibodies in convalescent plasma taken 1–10 months after SARS-CoV-2 infection. Longitudinal evaluation of total RBD IgG and neutralizing antibody revealed declining total antibody titers but improved neutralization potency per antibody to original SARS-CoV-2, indicative of antibody response maturation. Neutralization assays with authentic viruses revealed that early antibodies capable of neutralizing original SARS-CoV-2 had limited reactivity toward B.1.351 (501Y.V2) and P.1 (501Y.V3) variants. **Antibodies from late convalescents exhibited increased**

neutralization potency to VOCs, suggesting persistence of cross-neutralizing antibodies in plasma. Thus, maturation of the antibody response to SARS-CoV-2 potentiates cross-neutralizing ability to circulating variants, suggesting that declining antibody titers may not be indicative of declining protection [*emphasis added*]."

[435] ***Impact of SARS-CoV-2 variants on the total CD4+ and CD8+ T cell reactivity in infected or vaccinated individuals***
Cell Reports Medicine
Alison Tarke, John Sidney, *et al*.
July 1, 2021
https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(21)00204-4?

"**Highlights**: T cells of exposed donors or vaccinees effectively recognize SARS-CoV-2 variants

Summary: … [T]he SARS-CoV-2 variants analyzed here do not significantly disrupt the total SARS-CoV-2 T cell reactivity"

[436] ***SARS-CoV-2-specific T cell memory is sustained in COVID-19 convalescent patients for 10 months with successful development of stem cell-like memory T cells***
Nature Communications (Korea Advanced Institute of Science and Technology)
Jae Hyung Jung, Min-Seok Rha, *et al*.
June 30, 2021
https://www.nature.com/articles/s41467-021-24377-1

"**Abstract**: Memory T cells contribute to rapid viral clearance during re-infection, but the longevity and differentiation of SARS-CoV-2-specific memory T cells remain unclear. Here we conduct ex vivo assays to evaluate SARS-CoV-2-specific CD4+ and CD8+ T cell responses in COVID-19 convalescent patients **up to 317 days post-symptom onset (DPSO)**, and find that **memory T cell responses are maintained during the study period** regardless of the severity of COVID-19 [*emphasis added*]. In particular, we observe sustained polyfunctionality and proliferation capacity of SARS-CoV-2-specific T cells."

[437] ***Immunodominant T-cell epitopes from the SARS-CoV-2 spike antigen reveal robust pre-existing T-cell immunity in unexposed individuals***
Scientific Reports (Nature)
Swapnil Mahajan, Vasumathi Kode, *et al*.
June 23, 2021
https://www.nature.com/articles/s41598-021-92521-4

"**Abstract**: … In this study, we identified immunodominant CD8 T-cell epitopes in the spike antigen using a novel TCR-binding algorithm. The predicted epitopes induced robust T-cell activation in unexposed donors demonstrating pre-existing CD4 and CD8 T-cell immunity to SARS-CoV-2 antigen… [O]ur findings suggest that SARS-CoV-2 reactive T-cells are likely to be present in many individuals because of prior exposure to flu and CMV viruses."

[438] ***Necessity of COVID-19 vaccination in previously infected individuals***
Cleveland Clinic
Nabin K. Shrestha, Patrick C. Burke, *et al*.
June 19, 2021
https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3.full-text

"**Conclusions**: Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before.

Summary: Cumulative incidence of COVID-19 was examined among 52238 employees in an American healthcare system [*Cleveland Clinic Health System*]. COVID-19 did not occur in anyone over the five months of the study among 2579 individuals previously infected with COVID-19, **including 1359 who did not take the vaccine** [*emphasis added*]."

[439] ***SARS-CoV-2 elicits robust adaptive immune responses regardless of disease severity***
The Lancet
Stine SF Nielsen, Line K Vibholm, *et al*.
June 4, 2021
https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(21)00203-6/fulltext

"**Added value of this study**: In this context, we investigated, the adaptive immune response developed during SARS-CoV-2 infections in 203 recovered patients experiencing a full spectrum of disease severity, from asymptomatic infections to severe cases requiring hospitalization. The analysis of both binding and neutralization capacity of participant antibodies, alongside CD8+ T-cell responses, towards multiple SARS-CoV-2 epitopes, provides a broad characterization of the adapted response during primary virus infection. We found that the vast majority of recovered individuals have clearly detectable and functional SARS-CoV-2 spike specific adaptive immune responses, despite diverse disease severities…

Discussion: … Overall, our results show that the majority of patients developed a **robust and broad both humoral and cellular immune response** to SARS-CoV-2 [*emphasis added*]."

[440] **Research Letter: *Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy***
JAMA Internal Medicine (Magenta Hospital and Legnano Hospital, Italy)
Jose Vitale, Nicola Murnoli, *et al*.
May 28, 2021
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2780557

"**Methods**: We investigated the incidence of SARS-CoV-2 primary infection and reinfection among individuals who, during the first wave of the pandemic in Italy (February to July 2020), underwent diagnostic reverse-transcriptase–polymerase chain reaction (PCR)…

Results: … During the follow-up (mean [SD], 280 days) 5 reinfections … were confirmed in the cohort of 1579 positive patients…

Discussion: The study results suggest that reinfections are rare events and patients who have recovered from COVID-19 have a lower risk of reinfection. Natural immunity to SARS-CoV-2 appears to confer a protective effect for at least a year."

[441] **Email and FedEx to Rochelle P. Walensky, Director of the CDC: *re. CDC recommendations regarding the fully vaccinated***
Siri & Glimstad LLP (attorneys)
Aaron Siri, Elizabeth A. Brehm, Caroline Tucker, and Jessica Wallace
May 28, 2021
https://www.icandecide.org/wp-content/uploads/2021/10/Legal-update-July-6-petition.pdf

> "We write on behalf of our client and its members with regard to certain recently announced updates in CDC recommendations, reflected on the CDC's *When You've Been Fully Vaccinated* and *Interim Public Health Recommendations for Fully Vaccinated People* webpages. These recommendations apply to only fully vaccinated individuals. We write to request clarification that the additional 'freedoms' afforded to those that have been immunized will also be afforded to those that have had COVID-19 (the 'convalescent'). As outlined below and in the attached Declaration of Peter A. McCullough, MD, MPH, **restrictions on the rights and civil liberties of the convalescent** beyond the restrictions placed on the vaccinated **are not supported by the existing science** *[emphasis added]*."

[442] ***Quantifying the risk of SARS-CoV-2 reinfection over time***
Reviews in Medical Virology
Patricial Harrington and Mairin Ryan
May 27, 2021
https://onlinelibrary.wiley.com/doi/10.1002/rmv.2260

> "**Summary**: … To our knowledge, this is the first systematic review to synthesise the evidence on the risk of SARS-CoV-2 reinfection over time… Across studies, the total number of PCR-positive or antibody-positive participants at baseline was 615,777, and the maximum duration of follow-up was more than 10 months in three studies. **Reinfection was an uncommon event (absolute rate 0%–1.1%)**, with no study reporting an increase in the risk of reinfection over time… These data suggest that **naturally acquired SARS-CoV-2 immunity does not wane for at least 10 months post-infection** [*emphasis added*]."

[443] ***Had COVID? You'll probably make antibodies for a lifetime***
Nature magazine
Ewen Callaway
May 26, 2021
https://www.nature.com/articles/d41586-021-01442-9

> "Many people who have been infected with SARS-CoV-2 will probably make antibodies against the virus for most of their lives. So suggest researchers who have identified long-lived antibody-producing cells in the bone marrow of people who have recovered from COVID-19.
>
> The study provides evidence that immunity triggered by SARS-CoV-2 infection will be **extraordinarily long-lasting** [*emphasis added*]."

[444] ***SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans***
Nature magazine – Washington University School of Medicine
Jackson S. Turner, Wooseob Kim, *et al*.
May 24, 2021:
https://www.nature.com/articles/s41586-021-03647-4

"**Abstract**: … Consistently, circulating resting memory B cells directed against SARS-CoV-2 S were detected in the convalescent individuals. Overall, our results indicate that **mild infection with SARS-CoV-2 induces robust antigen-specific, long-lived humoral immune memory** in humans [*emphasis added*]."

[445] ***Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2***
Hospices Civils de Lyon (France)
Claudia Gonzalez, Carla Saade, *et al*.
May 11, 2021
https://www.medrxiv.org/content/10.1101/2021.05.11.21256578v1.full-text

"**Background**: … SARS-CoV-2 mutations appeared recently and can lead to conformational changes in the spike protein and probably induce modifications in antigenicity. In this study, we wanted to assess the neutralizing capacity of antibodies to prevent cell infection, using a live virus neutralisation test.

Methods: Sera samples were collected from different populations: two-dose vaccinated COVID-19-naïve healthcare workers (HCWs; Pfizer-BioNTech BNT161b2), 6-months post mild COVID-19 HCWs, and critical COVID-19 patients. We tested various clades such as 19A (initial one), 20B (B.1.1.241 lineage), 20I/501Y.V1 (B.1.1.7 lineage), and 20H/501Y.V2 (B.1.351 lineage).

Conclusion: Neutralisation capacity was slightly reduced for critical patients and HCWs 6-months post infection. No neutralisation escape could be feared concerning the two variants of concern in both populations. The **reduced neutralising response observed** towards the 20H/501Y.V2 in comparison with the 19A and 20I/501Y.V1 isolates **in fully immunized subjects with the BNT162b2 vaccine** is a striking finding of the study [*emphasis added*]."

[446] ***WHO scientific brief: COVID-19 natural immunity***
World Health Organization (WHO)
May 10, 2021
https://apps.who.int/iris/bitstream/handle/10665/341241/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf?sequence=3&isAllowed=y

"**Key Messages**:

- Within 4 weeks following infection, 90-99% of individuals infected with the SARS-CoV-2 virus develop detectable neutralizing antibodies.
- The strength and duration of the immune responses to SARS-CoV-2 are not completely understood and currently available data suggests that it varies by age and the severity of symptoms. Available scientific data suggests that in most people immune responses remain robust and protective against reinfection for at least

6-8 months after infection (the longest follow up with strong scientific evidence is currently approximately 8 months)."

[447] ***The BNT162b2 mRNA vaccine against SARS-CoV-2 reprograms both adaptive and innate immune responses***
Radhoud University Medical Center (Netherlands)
F. Konstantin Fohse, Busranur Geckin, *et al*.
May 6, 2021
https://www.medrxiv.org/content/10.1101/2021.05.03.21256520v1.full-text

"In conclusion, our data show that the BNT162b2 vaccine [*Pfizer/BioNTech*] induces effects on both the adaptive and the innate branch of immunity and that these effects are different for various SARS-CoV-2 strains. Intriguingly, the BNT162b2 vaccine induces reprogramming of innate immune responses as well, and this needs to be taken into account: in combination with strong adaptive immune responses, this could contribute to a more balanced inflammatory reaction during COVID-19 infection, or it may contribute to a **diminished innate immune response** towards the virus [*emphasis added*]."

[448] ***Discrete Immune Response Signature to SARS-CoV-2 mRNA Vaccination Versus Infection***
New York University
Ellie Ivanova, Joseph Devlin, *et al*.
May 3, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3838993

"**Abstract**: Both SARS-CoV-2 infection and vaccination elicit potent immune responses… While both infection and vaccination induced robust innate and adaptive immune responses, our analysis revealed significant qualitative differences between the two types of immune challenges."

[449] ***SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy***
EClinical Medicine published by the Lancet (Cornell University, Doha, Qatar)
Laith J. Abu-Raddad, Hiam Chemaitelly, *et al*.
April 27, 2021
https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00141-3/fulltext

"**Interpretation**: Reinfection is rare in the young and international population of Qatar. Natural infection appears to elicit strong protection against reinfection with an efficacy ~95% for at least seven months."

[450] ***Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel***
Sheba Medical Center (Israel)
Yair Goldberg, Micha Mandel, *et al*.
April 24, 2021
https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.full-text

"**Abstract**: … Vaccination was highly effective with overall estimated efficacy for documented infection of 92·8% (CI:[92·6, 93·0]); hospitalization 94·2% (CI:[93·6, 94·7]); severe illness 94·4% (CI:[93·6, 95·0]); and death 93·7% (CI:[92·5, 94·7]). Similarly, the overall estimated level of protection from prior SARS-CoV-2 infection for documented infection is 94·8% (CI:[94·4, 95·1]); hospitalization 94·1% (CI:[91·9, 95·7]); and severe illness 96·4% (CI:[92·5, 98·3]). Our results question the need to vaccinate previously-infected individuals."

[451] ***Assessment of protection against reinfection with SARS-CoV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level observational study***
The Lancet
Christian Holm Hansen, Daniela Michlmayr, Sophie Madeleine Gubbels, Kare Melbak, and Steen Ethelberg
March 27, 2021
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00575-4/fulltext

Background: … In 2020, as part of Denmark's extensive, free-of-charge PCR-testing strategy, approximately 4 million individuals (69% of the population) underwent 10·6 million tests. Using these national PCR-test data from 2020, we estimated protection towards repeat infection with SARS-CoV-2….

Discussion: We used a large national surveillance dataset of individually referable PCR test results to estimate the degree to which previous infection with SARS-CoV-2 results in protection against repeat infection. We found protection in the population to be **80% or higher in those younger than 65 years**, but to be approximately 47% in those aged 65 years and older. **We did not see signs of waning protection against repeat infection** within the year 2020 [*emphasis added*]."

[452] ***SARS-CoV-2 infection induces sustained humoral immune responses in convalescent patients following symptomatic COVID-19***
Nature Communications
Jun Wu, Boyun Liang, *et al*.
March 22, 2021
https://www.nature.com/articles/s41467-021-22034-1

"**Abstract**: … At late time points, the positivity rates for binding and neutralizing SARS-CoV-2-specific antibodies are still >70%. These data indicate sustained humoral immunity in recovered patients who had symptomatic COVID-19, suggesting prolonged immunity."

[453] ***Reinfection Rates Among Patients Who Previously Tested Positive for Coronavirus Disease 2019: A Retrospective Cohort Study***
Cleveland Clinic
Megan M. Sheehan, Anita J. Reddy, and Michael B. Rothberg
March 15, 2021
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab234/6170939

"**Conclusions**: Prior infection in patients with COVID-19 was highly protective against reinfection and symptomatic disease. **This protection increased over time** [*emphasis added*]...

Discussion: … Protection of prior infection against symptomatic disease was 85%; even when asymptomatic cases were included, protection offered against reinfection was 82%. Few patients were hospitalized following reinfection, and none with COVID-related symptoms required intensive care, suggesting a high level of protection against severe disease. Six months after infection, protection against symptomatic disease exceeded 90%."

[454] ***A majority of uninfected adults show preexisting antibody reactivity against SARS-CoV-2***
JCI Insight
Abdelilah Majdoubi, Christina Michalski, *et al*.
March 15, 2021
https://insight.jci.org/articles/view/146316/pdf

"**Introduction**: … While much attention has focused on defining immune reactivity in individuals after infection, other data indicate that many individuals show preexisting SARS-CoV-2 cross-reactive T and B cells without prior exposure to the virus…

Discussion: … The main finding in this study is that, at a population level, the vast majority of adults show anti-body reactivity against SARS-CoV-2 antigens… [I]t is extremely unlikely that this antibody reactivity results from a direct exposure to SARS-CoV-2. Moreover, findings of similar antibody reactivity in prepandemic adult sera and from sera obtained from infants younger than 1 year of age confirms that we are detecting genuine cross-reactivity rather than reactivity to SARS-CoV-2 from asymptomatic COVID-19 cases…

In conclusion, this study reveals **common preexisting, broadly reactive SARS-CoV-2 antibodies in uninfected adults** [*emphasis added*]."

[455] ***A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: a preliminary report***
Maccabi Healthcare Services (Israel)
Galit Perez, Tamar Banon, *et al*.
March 8, 2021
https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1

> "In this descriptive preliminary report, we conducted a large-scale assessment on the country level of the possible occurrence of COVID-19 reinfection within the members of a large healthcare provider in Israel. Out of 149,735 individuals with a documented positive PCR test between March 2020 and January 2021, 154 had two positive PCR tests at least 100 days apart, **reflecting a reinfection proportion of 1 per 1000** [*emphasis added*]. Given our strict inclusion criteria, we believe these numbers represent true reinfection incidence in MHS and should be clinically regarded as such."

[456] ***Robust SARS-CoV-2-specific T cell immunity is maintained at 6 months following primary infection***
Nature Immunology (University of Birmingham and National Infection Service, UK)
Jianmin Zuo, Alexander C. Dowell, *et al*.
March 5, 2021
https://www.nature.com/articles/s41590-021-00902-8

> "**Discussion**: The magnitude and quality of the immune memory response to SARS-CoV-2 will be critical in preventing reinfection. Here we undertook an assessment of SARS-CoV-2-specific T cell immune response at 6 months following primary infection in a unique cohort of healthy adults with asymptomatic or mild-to-moderate COVID-19… The major finding was that **virus-specific T cells were detectable in all donors at this extended follow-up period** [*emphasis added*]…
>
> The magnitude of T cell response was heterogeneous and may reflect diversity in the profile of T cell immunity during acute infection. A striking feature was that the magnitude of cellular immunity by ELISPOT was 50% higher in donors who had experienced symptomatic infection. This demonstrates that the initial 'set point' of cellular immunity established following acute infection is maintained for at least 6 months."

[457] ***SARS-CoV-2 re-infection risk in Austria***
European Journal of Clinical Investigation
Stefan Pilz, Ali Chakeri, *et al*.
February 13, 2021
https://onlinelibrary.wiley.com/doi/10.1111/eci.13520

> "**Conclusions**: We observed a relatively low re-infection rate of SARS-CoV-2 in Austria. **Protection** against SARS-CoV-2 **after natural infection is comparable with the highest available estimates on vaccine efficacies** [*emphasis added*].
>
> **Results**: From 15,424 patients with SARS-CoV-2 positive tests in the first wave, 584 were recorded as COVID-19 deaths, so that our COVID-19 survivor group consists of 14 840 patients…

During the observation period from September 1 to November 30, we recorded 40 tentative re-infections in the COVID-19 survivor group (**0.27%**), and 253,581 new infections in the general population group (**2.85%**) [*emphasis added*]…"

[458] ***Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers***
New England Journal of Medicine (Oxford University Hospitals Staff Testing Group)
Sheila F. Lumley, Deise O'Donnell, *et al*.
February 11, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2034545

"**Methods**: We investigated the incidence of SARS-CoV-2 infection confirmed by polymerase chain reaction (PCR) in seropositive and seronegative health care workers attending testing of asymptomatic and symptomatic staff at Oxford University Hospitals in the United Kingdom. Baseline antibody status was determined by anti-spike (primary analysis) and anti-nucleocapsid IgG assays, and staff members were followed for up to 31 weeks…

Results: A total of 12,541 health care workers participated and had anti-spike IgG measured; 11,364 were followed up after negative antibody results and 1265 after positive results... **There were no symptomatic infections in workers with anti-spike antibodies** [*emphasis added*]…

Conclusions: The presence of anti-spike or anti-nucleocapsid IgG antibodies was associated with a substantially reduced risk of SARS-CoV-2 reinfection in the ensuing 6 months."

[459] ***Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection***
Science magazine (La Jolla Institute for Immunology)
Jennifer M. Dan, Jose Mateus, *et al*.
February 5, 2021
https://www.science.org/doi/10.1126/science.abf4063

"**Variable memory**

Immune memory against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) helps to determine protection against reinfection, disease risk, and vaccine efficacy. Using 188 human cases across the range of severity of COVID-19, Dan et al. analyzed cross-sectional data describing the dynamics of SARS-CoV-2 memory B cells, CD8+ T cells, and CD4+ T cells for more than 6 months after infection. The authors found a high degree of heterogeneity in the magnitude of adaptive immune responses that persisted into the immune memory phase to the virus. However, immune memory in three immunological compartments remained measurable in greater than 90% of subjects for more than 5 months after infection. Despite the heterogeneity of immune responses, these results show that **durable immunity** against secondary COVID-19 disease is a possibility for most individuals…

This is the **largest antigen-specific study to date** of the four major types of immune memory for any viral infection [*emphasis added*]."

[460] ***Lasting immunity found after recovery from COVID-19***
National Institutes of Health (NIH)
Sharon Reynolds
January 26, 2021
https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19

> "The immune systems of more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection…
>
> The researchers found **durable immune responses** in the majority of people studied [*emphasis added*]. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset...
>
> Virus-specific B cells increased over time. People had more memory B cells six months after symptom onset than at one month afterwards…
>
> Levels of T cells for the virus also remained high after infection. Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus."

[461] ***Cellular Immunity in COVID-19 Convalescents with PCR-Confirmed Infection but with Undetectable SARS-CoV-2–Specific IgG***
University of Duisburg-Essen
Sina Schwarzkopf, Adalbert Krawczyk, *et al*.
January 2021
https://wwwnc.cdc.gov/eid/article/27/1/20-3772_article

> "**Abstract**: We investigated immune responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) among a group of convalescent, potential blood donors in Germany who had PCR-confirmed SARS-CoV-2 infection… Using interferon-γ ELISpot, we observed that 78% of PCR-positive volunteers with undetectable antibodies showed T cell immunity against SARS-CoV-2. We observed a similar frequency (80%) of T-cell immunity in convalescent donors with strong antibody responses but did not detect immunity in negative controls. We concluded that, in convalescent patients with undetectable SARS-CoV-2 IgG, immunity may be mediated through T cells."

[462] ***Intrafamilial Exposure to SARS-CoV-2 Associated with Cellular Immune Response without Seroconversion, France***
Emerging Infectious Diseases
Floriane Gallais, Aurelie Velay, *et al*.
January 2021
https://wwwnc.cdc.gov/eid/article/27/1/20-3611_article

> "**Abstract**: We investigated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)–specific antibodies and T-cell responses against SARS-CoV-2…
>
> **Discussion**: In this study, we demonstrate that intrafamilial contacts can display a SARS-CoV-2–specific T-cell response in the absence of seroconversion, especially when they have been symptomatic. This T-cell response provides evidence that transient or anatomically contained SARS-CoV-2 infection, or both, may have occurred and that T-cell responses would be more sensitive indicators of SARS-Co-V-2 exposure than antibodies…

Overall, our results indicate that persons exposed to SARS-CoV-2 may develop virus-specific T-cell responses without detectable circulating antibodies. This aspect of the immune response against SARS-CoV-2 contributes substantially to the understanding of the natural history of COVID-19. Furthermore, our data indicate that epidemiologic data relying solely on the detection of SARS-CoV-2 antibodies may lead to a **substantial underestimation of prior exposure to the virus** [*emphasis added*]."

[463] ***Cellular immunity to SARS-CoV-2 found at six months in non-hospitalised individuals***
UK Coronavirus Immunology Consortium (UK-CIC), Public Health England and Manchester University NHS Foundation Trust
November 2, 2020
https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals

"[R]esearchers… collected serum and blood samples from a cohort of more than 2,000 clinical and non-clinical healthcare workers including 100 individuals who tested sero-positive for SARS-CoV-2 in March/April 2020… [T] this study of 100 individuals is one of the largest in the world to date in this field…

T cell responses were present in all individuals at six months after SARS-CoV-2 infection. The cellular immune response was directed against a range of proteins from the virus, including the Spike protein that is being used in most vaccine studies. However, comparable immunity was present against additional proteins, such as nucleoprotein, which suggests that these may be of value for incorporation in future vaccine protocols. This indicates that **a robust cellular memory against the virus persists for at least six months** [*emphasis added*]…"

[464] ***Selective and cross-reactive SARS-CoV-2 T cell epitopes in unexposed humans***
Science magazine
Jose Mateus, Alba Grifoni, *et al*.
October 2, 2020
https://www.science.org/lookup/doi/10.1126/science.abd3871

"**Abstract**: Many unknowns exist about human immune responses to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. SARS-CoV-2–reactive CD4+ T cells have been reported in unexposed individuals, suggesting **preexisting cross-reactive T cell memory in 20 to 50% of people** [*emphasis added*]. However, the source of those T cells has been speculative. Using human blood samples derived before the SARS-CoV-2 virus was discovered in 2019, we mapped 142 T cell epitopes across the SARS-CoV-2 genome to facilitate precise interrogation of the SARS-CoV-2–specific CD4+ T cell repertoire. We demonstrate a range of preexisting memory CD4+ T cells that are cross-reactive with comparable affinity to SARS-CoV-2 and the common cold coronaviruses human coronavirus (HCoV)-OC43, HCoV-229E, HCoV-NL63, and HCoV-HKU1. Thus, variegated T cell memory to coronaviruses that cause the common cold may underlie at least some of the extensive heterogeneity observed in coronavirus disease 2019 (COVID-19) disease."

[465] ***Immune cells for common cold may recognize SARS-CoV-2***
National Institutes of Health (NIH)
Tianna Hicklin
August 18, 2020
https://www.nih.gov/news-events/nih-research-matters/immune-cells-common-cold-may-recognize-sars-cov-2

> "Previous studies have reported that 20–50% of people who hadn't been exposed to SARS-CoV-2 showed T cell responses against different parts of the SARS-CoV-2 virus. To investigate further, a research team led by Drs. Alessandro Sette and Daniela Weiskopf at the La Jolla Institute for Immunology tested blood samples collected between March 2015 and March 2018 for T-cell responses against different pieces of SARS-CoV-2…
>
> [The researchers] found that of the SARS-CoV-2 and 'common cold' coronavirus fragments that were most similar (at least 67% genetic similarity) 57% showed cross-reactivity by memory T cells.
>
> 'We have now proven that, in some people, **pre-existing T cell memory against common cold coronaviruses can cross-recognize SARS-CoV-2**, down to the exact molecular structures [*emphasis added*],' Weiskopf says. 'This could help explain why some people show milder symptoms of disease while others get severely sick.'"

[466] ***Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19***
Cell
Takuya Sekine, Andre Perez-Potti, *et al*.
August 14, 2020
https://www.cell.com/cell/fulltext/S0092-8674(20)31008-4

> "**Summary**: SARS-CoV-2-specific memory T cells will likely prove critical for long-term immune protection against COVID-19. Here, we systematically mapped the functional and phenotypic landscape of SARS-CoV-2-specific T cell responses in unexposed individuals, exposed family members, and individuals with acute or convalescent COVID-19… Our collective dataset shows that SARS-CoV-2 elicits broadly directed and functionally replete memory T cell responses, suggesting that natural exposure or infection may prevent recurrent episodes of severe COVID-19."

[467] ***Primary exposure to SARS-CoV-2 protects against reinfection in rhesus macaques***
Science (Beijing Union Medical College)
Wei Deng, Linlin Bao, *et al*.
August 14, 2020
https://www.science.org/doi/10.1126/science.abc5343

> "**Abstract**: … Rhesus macaques reinfected with the identical SARS-CoV-2 strain during the early recovery phase of the initial SARS-CoV-2 infection did not show detectable viral dissemination, clinical manifestations of viral disease, or histopathological changes. Comparing the humoral and cellular immunity between primary infection and rechallenge revealed notably enhanced neutralizing antibody and immune responses. Our results suggest that primary SARS-CoV-2 exposure protects against subsequent reinfection in rhesus macaques."

[468] ***SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls***
Nature magazine
Nina Le Bert, Anthony T. Tan, *et al*.
July 15, 2020
https://www.nature.com/articles/s41586-020-2550-z

"**Abstract**: Memory T cells induced by previous pathogens can shape susceptibility to, and the clinical severity of, subsequent infections. Little is known about the presence in humans of pre-existing memory T cells that have the potential to recognize severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Here we studied T cell responses against the structural (nucleocapsid (N) protein) and non-structural (NSP7 and NSP13 of ORF1) regions of SARS-CoV-2 in individuals convalescing from coronavirus disease 2019 (COVID-19) (n = 36). In all of these individuals, we found CD4 and CD8 T cells that recognized multiple regions of the N protein. Next, we showed that patients (n = 23) who recovered from SARS (the disease associated with SARS-CoV infection) possess long-lasting memory T cells that are reactive to the N protein of SARS-CoV **17 years after** the outbreak of SARS in 2003; **these T cells displayed robust cross-reactivity to the N protein of SARS-CoV-2** [*emphasis added*]. We also detected SARS-CoV-2-specific T cells in individuals with no history of SARS, COVID-19 or contact with individuals who had SARS and/or COVID-19 (n = 37)… Thus, infection with betacoronaviruses induces multi-specific and long-lasting T cell immunity against the structural N protein."

[469] ***Cross-neutralization of SARS-CoV-2 by a human monoclonal SARS-CoV antibody***
Nature magazine
Dora Pinto, Young-Jun Park, *et al*.
May 18, 2020
https://www.nature.com/articles/s41586-020-2349-y

"**Abstract**: … The SARS-CoV-2 spike (S) glycoprotein promotes entry into host cells and is the main target of neutralizing antibodies. Here we describe **several monoclonal antibodies that target the S glycoprotein of SARS-CoV-2**, which we identified from memory B cells of an individual who was infected with severe acute respiratory syndrome coronavirus (SARS-CoV) in 2003 [*emphasis added*]. One antibody (named S309) potently neutralizes SARS-CoV-2 and SARS-CoV pseudoviruses as well as authentic SARS-CoV-2, by engaging the receptor-binding domain of the S glycoprotein."

[470] ***Targets of T Cell Responses to SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals***
Cell
Alba Grifoni, Daniela Weiskopf, *et al*.
May 14, 2020
https://www.cell.com/cell/fulltext/S0092-8674(20)30610-3

"**Highlights**:

- Epitope pools detect CD4+ and CD8+ T cells in 100% and 70% of convalescent COVID patients
- T cell responses are focused not only on spike but also on M, N, and other ORFs
- T cell reactivity to SARS-CoV-2 epitopes is also detected in non-exposed individuals

Summary: … Importantly, we detected SARS-CoV-2-reactive CD4+ T cells in ~40%–60% of **unexposed individuals**, suggesting cross-reactive T cell recognition between circulating 'common cold' coronaviruses and SARS-CoV-2 [*emphasis added*]."

‘Breakthrough’ Cases, Hospitalizations and Deaths

[471] **ADDED since 2/8/2022**
Video (2m): *Experts and talking heads claim covid vaccines stop transmission compilation*
Publius1215
October 17, 2021
https://rumble.com/v1oc7us-experts-and-talking-heads-claim-covid-vaccines-stop-transmission-compilatio.html

[472] **ADDED since 2/8/2022**
Video (2m): *They Lied about the mRNA Vaccines*
KanekoaTheGreat
November 18, 2021
https://rumble.com/vpeqy0-the-covid-19-vaccine-booster-circus.html
Description: Another compilation of government officials, media personalities, and others falsely asserting the inoculations stop COVID-19 transmissions, hospitalizations, and deaths.

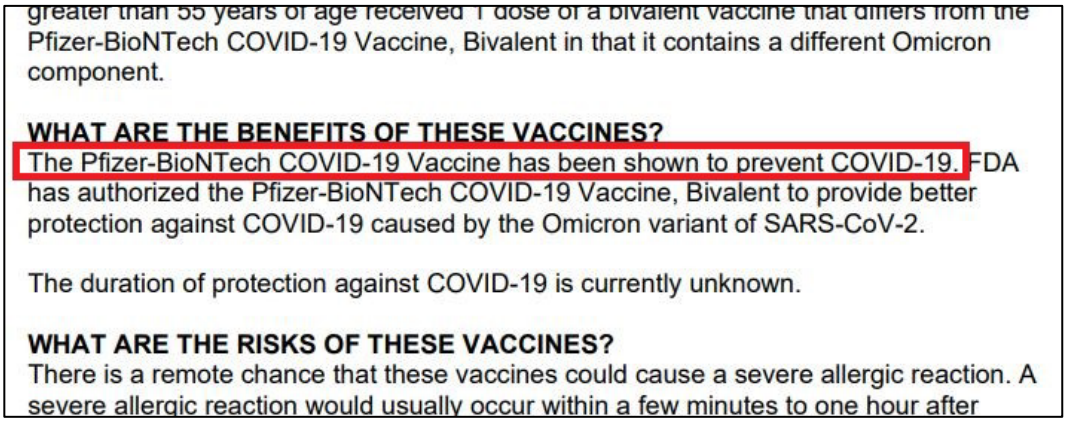
[473] **ADDED since 2/8/2022**
Video (2m): *Dr. Deborah Birx says she 'knew' COVID vaccines would not 'protect against infection'*
Fox News
Interview with Dr. Deborah Birx, former White House COVID response coordinator
July 22, 2022
https://www.foxnews.com/media/dr-deborah-birx-knew-covid-vaccines-not-protect-against-infection

> **Birx**: “**I knew** these vaccines were not going to protect against infection. And I think we overplayed the vaccines, and it made people then worry that it's not going to protect against severe disease and hospitalization.”

[474] **ADDED since 2/8/2022**

FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZERBIONTECH COVID-19 VACCINE AND THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 6 MONTHS THROUGH 4 YEARS OF AGE

Pfizer, Inc.
Revised December 8, 2022
https://labeling.pfizer.com/ShowLabeling.aspx?id=17228



greater than 55 years of age received 1 dose of a bivalent vaccine that differs from the Pfizer-BioNTech COVID-19 Vaccine, Bivalent in that it contains a different Omicron component.

WHAT ARE THE BENEFITS OF THESE VACCINES?

The Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19. FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide better protection against COVID-19 caused by the Omicron variant of SARS-CoV-2.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THESE VACCINES?

There is a remote chance that these vaccines could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after

[475] ***COVID-19 Vaccine Breakthrough Case Investigation and Reporting***
Centers for Disease Control and Prevention
https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html

> "**Defining a vaccine breakthrough infection**: For the purpose of this surveillance, a **vaccine breakthrough infection** is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person **≥14 days after they have completed all recommended doses** of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine..."
>
> As of May 1, 2021, CDC transitioned from monitoring all reported vaccine breakthrough cases to focus on identifying and investigating **only hospitalized or fatal cases** due to any cause [*emphasis added*]."

[476] ***The Possibility of COVID-19 after Vaccination: Breakthrough Infections***
Centers for Disease Control and Prevention
Updated September 7, 2021
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html

> "People who get vaccine breakthrough infections can be contagious."

[477] ***Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England***
Public Health England
Jamie Lopez Bernal, Nick Andrews, *et al*.
March 2, 2021
https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1.full-text

"**Participants**: All adults in England aged 70 years and older (over 7.5 million). All COVID-19 testing in the community among eligible individuals who reported symptoms between 8th December 2020 and 19th February 2021 was included in the analysis…

Results: Individuals aged >=80 years vaccinated with BNT162b2 prior to 4th January, had a higher odds of testing positive in the first 9 days after vaccination (odds ratio up to 1.48, 95%CI 1.23-1.77), indicating that those initially targeted had a higher underlying risk of infection...

Individuals aged >=70 years vaccinated from 4th January had a similar underlying risk of COVID-19 to unvaccinated individuals…

Results for BNT162b2 for vaccinations administered prior to the 4th of January are shown in Table 2 and Figure 2, this analysis was restricted to 80+ year olds as younger age groups were not eligible for vaccination prior to 4th of January. The **odds of testing positive among vaccinated individuals increased** during the early period up to days 7-9, reaching 1.48 (95%CI 1.23-1.77) [*emphasis added – see Table 2 below*]."

Note: 1.0 is the standard rate without inoculations.

Table 2: Adjusted odds ratios for confirmed case by interval after vaccination for BNT162b2, vaccinations administered prior to 4th January 2021, age >=80 years

Interval after dose (days)		Vaccinated prior to 4th Jan				
		controls	cases	OR (95% CI)	aOR (95% CI)	OR vs day 4-9
	unvaccinated	15,718	8,988	base	base	
dose 1	d1:0-3	277	167	1.17 (0.96-1.42)	1.22 (1.00-1.48)	
	d1:4-6	241	179	1.26 (1.03-1.54)	1.28 (1.05-1.56)	
	d1:7-9	252	257	1.47 (1.23-1.76)	1.48 (1.23-1.77)	
	d1:10-13	361	284	1.12 (0.95-1.31)	1.13 (0.96-1.33)	0.82 (0.67-1.01)
	d1:14-20	462	336	1.03 (0.89-1.19)	1.06 (0.92-1.23)	0.77 (0.63-0.94)
	d1:21-27	288	118	0.60 (0.48-0.75)	0.64 (0.51-0.79)	0.46 (0.35-0.60)
	d1:28-34	290	72	0.40 (0.30-0.52)	0.41 (0.32-0.54)	0.30 (0.22-0.41)
	d1:35-41	274	65	0.45 (0.34-0.60)	0.49 (0.37-0.66)	0.36 (0.26-0.49)
	d1:42+	396	59	0.34 (0.25-0.47)	0.39 (0.29-0.55)	0.28 (0.20-0.40)
dose 2	d2:0-3	116	45	0.55 (0.39-0.77)	0.59 (0.41-0.83)	0.42 (0.29-0.62)
	d2:4-6	80	30	0.52 (0.34-0.80)	0.57 (0.37-0.88)	0.41 (0.26-0.65)
	d2:7-13	201	28	0.20 (0.13-0.29)	0.21 (0.14-0.32)	0.15 (0.10-0.23)
	d2:14+	634	41	0.13 (0.09-0.18)	0.15 (0.11-0.21)	0.11 (0.07-0.15)

d1= interval after dose 1, d2= interval after dose 2. OR: odds ratios period adjusted by week of onset. aOR: odds ratios adjusted for age, period, sex, region, ethnicity, care home, imd quintile

[478] **ADDED since 2/8/2022**

FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine

US Food & Drug Administration

December 11, 2020

https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

> "At this time, **data are not available** to make a determination about how long the vaccine will provide protection, **nor is there evidence** that the vaccine prevents transmission of SARS-CoV-2 from person to person."

[479] ***COVID-19 Vaccine Breakthrough Case Investigation and Reporting***
Centers for Disease Control and Prevention (CDC)
Page last reviewed September 29, 2021
https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html

"**Defining a vaccine breakthrough infection**: For the purpose of this surveillance, a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person **≥14 days after they have completed all recommended doses** of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine [*emphasis added*]."

Note: So by definition, anyone getting a one-shot COVID-19 'vaccination series' cannot be counted as a breakthrough case until 14 days after their inoculation. Similarly, people getting a two-shot 'vaccination series' cannot be counted as a breakthrough case until 14 days after their second inoculation. Thus, in a system that 1) adheres to this CDC definition, and 2) categorizes COVID-19 cases in a binary scheme (e.g., 'vaccinated' vs. 'unvaccinated'), inoculation recipients testing positive at the 13-day mark or earlier are counted as **not** vaccinated. For an example, see '**King County, WA: *COVID-19 Outcomes by Vaccination Status***' below.

[480] **King County, WA: *COVID-19 Outcomes by Vaccination Status***
King County government
As of October 3, 2021
https://kingcounty.gov/depts/health/covid-19/data/vaccination-outcomes.aspx

Note: To view the following definitions, click **Open data notes**.

'"**Fully vaccinated individuals**: individuals who received their last recommended dose of a COVID-19 vaccine and have had at least 14 days to establish protection. Fully vaccinated cases includes [*sic*] only individuals who have tested positive for COVID-19 (either a PCR test or an antigen test) at least 14 days **after** they completed their vaccination series.

Not fully vaccinated individuals: individuals who have not received any vaccine doses, individuals who have started their vaccine series, and individuals who have completed their vaccination series within the past 14 days. Residents not currently eligible (under the age of 12 years old) are considered 'not fully vaccinated.'"

Note: The citations below are presented in reverse, chronological order.

[481] **ADDED since 2/8/2022**

Appendix 1: estimation of number needed to vaccinate to prevent a COVID-19 hospitalisation for primary vaccination, booster vaccination (3rd dose), autumn 2022 and spring 2023 booster for those newly in a risk group

UK Health Security Agency (UKHSA)

January 25, 2023

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1131409/appendix-1-of-jcvi-statement-on-2023-covid-19-vaccination-programme-8-november-2022.pdf

This Appendix is "[b]ased on a UK Health Security Agency (UKHSA) presentation to the Joint Committee on Vaccination and Immunisation (JCVI) on 25 October 2022."

"In order to consider the benefits of continued offers of primary vaccination, booster vaccination, the autumn booster, and potential boosting in the spring of 2023 (for example, for those newly entering a risk group) calculation of numbers needed to vaccinate (NNV) were completed…"

Table 4: NNV for prevention of severe hospitalisation for different programmes

	Programme			
Age	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
5 to 11	112200			
12 to 15	162600			
16 to 19	106500	193500	185100	
20 to 29	166200	418100	275200	
30 to 39	87600	188500	217300	
40 to 49	53700	40600	175900	
50 to 59	18700	16200	48300	
60 to 69	5700	9200	27300	
70+	2500	10400	7500	
In a risk group	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
20 to 29	11400	43500	59500	59500
30 to 39	10700	28600	40500	40500
40 to 49	9400	10600	49800	49800
50 to 59	5600	6100	18600	18600
No risk group	Primary	Booster (2+1)	Autumn 2022 boost	Spring 2023 boost
20 to 29	no cases	no cases	706500	
30 to 39	318400	no cases	no cases	
40 to 49	186800	190400	932500	
50 to 59	51600	107000	256400	

[482] **ADDED since 2/8/2022**

Survey: *'Died Suddenly'? More Than 1-in-4 Think Someone They Know Died From COVID-19 Vaccines*

Rasmussen Reports

January 2, 2023

https://www.rasmussenreports.com/public_content/politics/public_surveys/died_suddenly_more_than_1_in_4_think_someone_they_know_died_from_covid_19_vaccines

> "The latest Rasmussen Reports national telephone and online survey finds that 49% of American Adults believe it is likely that side effects of COVID-19 vaccines have caused a significant number of unexplained deaths, including 28% who think it's Very Likely…
>
> **Twenty-eight percent (28%) of adults** say they personally know someone whose death they think may have been caused by side effects of COVID-19 vaccines, while 61% don't and another 10% are not sure...
>
> The survey of 1,000 American Adults was conducted on December 28-30, 2022 by Rasmussen Reports…
>
> Similarly, while 45% of those who have not been vaccinated against COVID-19 think someone they know personally might have died from vaccine side effects, only 22% of vaccinated adults think so."

[483] **ADDED since 2/8/2022**

NSW COVID-19 Weekly Data Overview: Epidemiological weeks 51 and 52, ending 31 December 2022

New South Wales Ministry of Health

December 31, 2022

https://www.health.nsw.gov.au/Infectious/covid-19/Documents/weekly-covid-overview-20221231.pdf

> "Of the 95 people who were reported to have died with COVID-19, **72 (76%) were known to have received three or more doses of a COVID-19 vaccine**, while 9 had received two doses, 1 had received one dose and 6 had received no doses of a COVID-19 vaccine. The vaccination status of the remaining 7 were unable to be determined."

NSW COVID-19 WEEKLY DATA OVERVIEW

www.health.nsw.gov.au/coronavirus

Epidemiological weeks 51 and 52, ending 31 December 2022

Table 1. People with a COVID-19 diagnosis in the previous 14 days who were admitted to hospital, admitted to ICU or reported as having died in the two weeks ending 31 December 2022

	Admitted to hospital (but not to ICU)	Admitted to ICU	Deaths
Gender			
Female	842	63	42
Indeterminate	1	0	0
Male	936	77	53
Age group (years)			
0-9	85	3	0
10-19	24	3	0
20-29	67	8	1
30-39	79	7	0
40-49	64	6	0
50-59	105	17	3
60-69	199	27	8
70-79	436	42	19
80-89	507	24	31
90+	213	3	33
Local Health District of residence*			
Central Coast	113	3	5
Illawarra Shoalhaven	135	8	7
Nepean Blue Mountains	82	7	2
Northern Sydney	165	12	9
South Eastern Sydney	184	13	11
South Western Sydney	190	18	13
Sydney	157	10	5
Western Sydney	165	26	8
Far West	20	0	0
Hunter New England	176	16	16
Mid North Coast	76	5	3
Murrumbidgee	59	7	1
Northern NSW	77	3	8
Southern NSW	54	2	1
Western NSW	94	6	4
Vaccination status^			
Four or more doses	810	58	53
Three doses	377	29	19
Two doses	218	17	9
One dose	10	1	1
No dose	0	0	6
Unknown	364	35	7
Total	**1779**	**140**	**95**

*Excludes cases in correctional settings

^Vaccination status is determined by matching to Australian Immunisation Register (AIR) data. Name and date of birth need to be an exact match to that recorded in AIR for vaccination status to be determined. People with unknown vaccination status were those unable to be found in AIR. This may occur when names in AIR are different, for example shortened name or different spelling, to those used for the COVID-19 notification.

[484] **ADDED since 2/8/2022**

Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine

Cleveland Clinic

Nabin K. Shrestha, Patrick C. Burke, *et al*.

December 19, 2022

https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full

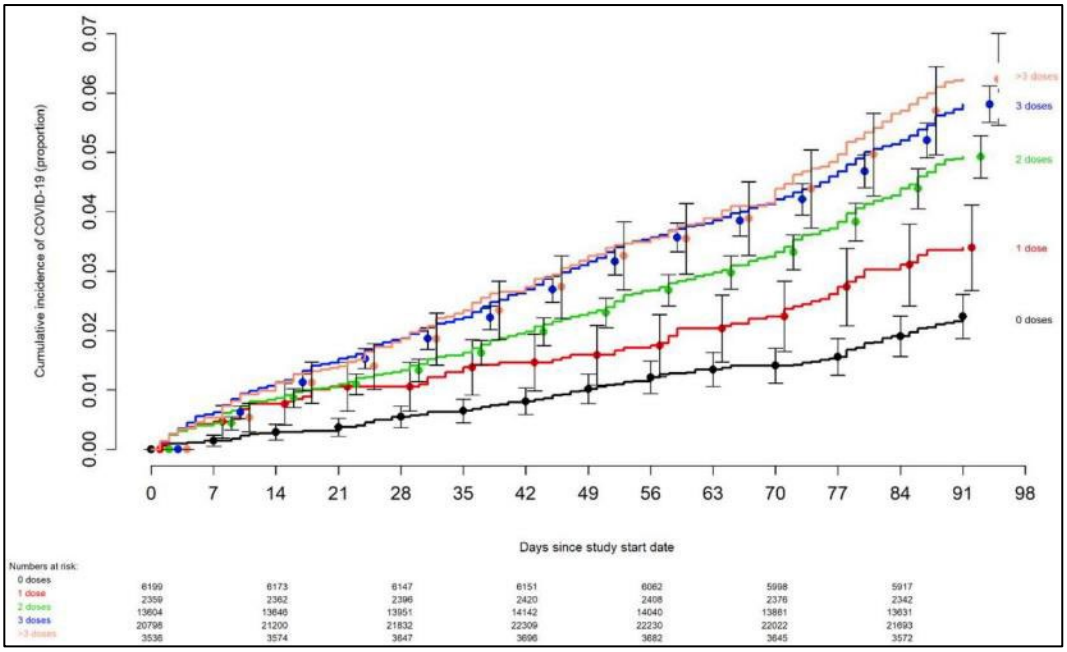
"**Background**: The purpose of this study was to evaluate whether a bivalent COVID-19 vaccine protects against COVID-19.

Methods: Employees of Cleveland Clinic in employment on the day the bivalent COVID-19 vaccine first became available to employees, were included. The cumulative incidence of COVID-19 was examined over the following weeks…

Introduction: … Recognition that the original COVID-19 vaccines provided much less protection after the emergence of the Omicron variant, spurred efforts to produce newer vaccines that were more effective. These efforts culminated in the approval by the US Food and Drug Administration, on 31 August 2022, of bivalent COVID-19 mRNA vaccines, which contained antigens represented in the original vaccine as well as antigens representing the BA.4/BA.5 lineages of the Omicron variant. Given the demonstrated safety of the earlier mRNA vaccines and the perceived urgency of need of a more effective preventive tool, these vaccines were approved **without** demonstration of effectiveness in clinical studies.

The purpose of this study was to evaluate whether the bivalent COVID-19 vaccine protects against COVID-19...

Results: … The risk of COVID-19 also varied by the number of COVID-19 vaccine doses previously received. The higher the number of vaccines previously received, the **higher the risk of contracting COVID-19** (Figure 2)…



Discussion: … The association of increased risk of COVID-19 with higher numbers of prior vaccine doses in our study, was unexpected. A simplistic explanation might be that those who received more doses were more likely to be individuals at higher risk of COVID-19. A small proportion of individuals may have fit this description. However, the majority of subjects in this study were generally young individuals and all were eligible to have received at least 3 doses of vaccine by the study start date, and which they had every opportunity to do. Therefore, those who received fewer than 3 doses (>45% of individuals in the study) were not those ineligible to receive the vaccine, but those who chose not to follow the CDC's recommendations on remaining updated with COVID-19 vaccination, and one could reasonably expect these individuals to have been more likely to have exhibited higher risk-taking behavior. Despite this, their risk of acquiring COVID-19 was lower than those who received a larger number of prior vaccine doses. This is **not** the only study to find a possible association with more prior vaccine doses and higher risk of COVID-19. A large study found that those who had an Omicron variant infection after previously receiving three doses of vaccine had a higher risk of reinfection than those who had an Omicron variant infection after previously receiving two doses of vaccine]. Another study found that receipt of two or three doses of a mRNA vaccine following prior COVID-19 was associated with a higher risk of reinfection than receipt of a single dose. We still have a lot to learn about protection from COVID-19 vaccination, and in addition to a vaccine's effectiveness it is important to examine whether multiple vaccine doses given over time may not be having the beneficial effect that is generally assumed."

[485] **ADDED since 2/8/2022**

Effectiveness of mRNA-1273 against infection and COVID-19 hospitalization with SARS-CoV-2 Omicron subvariants: BA.1, BA.2, BA.2.12.1, BA.4, and BA.5

Kaiser Permanente Southern California

December 2, 2022

https://www.medrxiv.org/content/10.1101/2022.09.30.22280573v2.full-text

"**Abstract**: Studies have reported reduced natural SARS-CoV-2 infection- and vaccine-induced neutralization against Omicron BA.4/BA.5 compared with earlier Omicron subvariants. We conducted a test-negative case–control study evaluating mRNA-1273 vaccine effectiveness (VE) against infection and hospitalization with Omicron subvariants. The study included 30,809 SARS-CoV-2 positive and 92,427 SARS-CoV-2 negative individuals aged ≥ 18 years tested during 1/1/2022-6/30/2022…

Results: … In analyses of 3-dose VE (versus unvaccinated) against infection with Omicron subvariants by time since vaccination, the 3-dose VE against BA.1 ranged from 85.8% (95% confidence interval [CI] 82.7%, 88.3%) in the 14-30 days after the third dose to 54.9% (95% CI 35.6%, 68.4%) >150 days after the third dose (Fig. 2, Supplementary Table 2a). VE for these two time intervals, respectively, was 61.0% (95% CI 27.6%, 79.0%) and **-24.9%** (95% CI -32.3%, -16.7%) for BA.2, excluding BA.2.12.1; 82.7% (95% CI 44.2%, 94.7%) and **-26.8%** (95% CI -34.6%, -18.0%) for BA.2.12.1; 72.6% (95% CI - 54.7%, 96.6%) and **-16.4%** (95% CI -35.8%, 8.2%) for BA.4; and 90.6% (95% CI 30.6%, 98.7%) and **-17.9%** (95% CI -29.6%, -4.2%) for BA.5. We also present the relative VE (rVE) comparing 3 doses to 2 doses against Omicron subvariants by time since vaccination (Fig. 2, Supplementary Table 2b). In general, we observed consistent incremental protection of 3 doses versus 2 doses in the 14-90 days after the third dose, other than against BA.4, which had a small number of cases and wide CI.

The incremental benefit in protection decreased by time since the third dose. For BA.5, the 95% CI of rVE included 0 after >90 days after the third dose."

[486] **ADDED since 2/8/2022**

Why Do Vaccinated People Represent Most COVID-19 Deaths Right Now?

Kaiser Family Foundation
Cynthia Cox Follow, Krutika Amin Follow, Jennifer Kates, and Josh Michau
November 30, 2022
https://www.kff.org/policy-watch/why-do-vaccinated-people-represent-most-covid-19-deaths-right-now/

"The share of COVID-19 deaths among those who are vaccinated has risen. In fall 2021, about 3 in 10 adults dying of COVID-19 were vaccinated or boosted. But by January 2022, as we showed in an analysis posted on the Peterson-KFF Health System Tracker, about 4 in 10 deaths were vaccinated or boosted. By April 2022, the United States Centers for Disease Control and Prevention (CDC) data show that about 6 in 10 adults dying of COVID-19 were vaccinated or boosted, and that's remained true through at least August 2022 (the most recent month of data)…

In order to be counted as vaccinated, a person must be at least **two weeks out** from completing their primary series before testing positive (for example, at least 14 days after completing two doses of the mRNA vaccine). Similarly, to be counted as having a booster, a person must be at least two weeks out from their booster or additional dose before testing positive."

[487] **ADDED since 2/8/2022**

Waning of first- and second-dose ChAdOx1 and BNT162b2 COVID-19 vaccinations: a pooled target trial study of 12.9 million individuals in England, Northern Ireland, Scotland and Wales

International Journal of Epidemiology — University of Edinburgh
Steven Kerr, Stuart Bedston, *et al*.
October 22, 2022
https://academic.oup.com/ije/advance-article/doi/10.1093/ije/dyac199/6770060

"**Background**: … We undertook a pooled analysis across the four nations of the UK to investigate waning in vaccine effectiveness (VE) and relative vaccine effectiveness (rVE) against severe COVID-19 outcomes…

Key Messages: We undertook an observational epidemiological analysis of the effectiveness of COVID-19 vaccines across all four nations of the UK, pooling data from a UK cohort of 12.9 million individuals.

Discussion: We carried out a pooled epidemiological analysis of linked, pseudonymized national-level vaccination data across the four nations of the UK. We employed a novel methodology to allow a pooled study to be done with only count data being shared between each country's TREs. We found evidence of waning in VE/rVE for Doses 1 and 2 of ChAdOx1 and Dose 1 of BNT162b2, with VE/rVE dropping to zero ~60–80 days after the date of administration and **becoming negative thereafter**. Our rVE estimates for Dose 2 of BNT162b2 remained above zero throughout 98 days of follow-up.

We believe that the most likely explanation for negative VE/rVE is that vaccination caused recipients to believe they were protected, leading them to change their behaviour in ways that increase their chance of contracting the infection. These changes in behaviours should initially have been outweighed by the protection offered by the immune response stimulated by the vaccine, but as time progressed the protection is likely to have diminished such that the impact of behavioural changes may have become dominant. It is also possible that naturally acquired immunity provides more robust protection than vaccination."

[488] **ADDED since 2/8/2022**

Waning of vaccine effectiveness against moderate and severe covid-19 among adults in the US from the VISION network: test negative, case-control study

British Medical Journal — Centers for Disease Control and Prevention COVID-19 Response Team

Jill M. Ferdinands, Brian E. Dixon, *et al*.

October 3, 2022

https://www.bmj.com/content/379/bmj-2022-072141

"**Objective**: To estimate the effectiveness of mRNA vaccines against moderate and severe covid-19 in adults by time since second, third, or fourth doses, and by age and immunocompromised status…

Results: 45 903 people admitted to hospital with covid-19 (cases) were compared with 213 103 people with covid-like illness who tested negative for SARS-CoV-2 (controls), and 103 287 people admitted to emergency department or urgent care with covid-19 (cases) were compared with 531 168 people with covid-like illness who tested negative for SARS-CoV-2. In the omicron period, vaccine effectiveness against covid-19 requiring admission to hospital was 89% (95% confidence interval 88% to 90%) within two months after dose 3 but waned to 66% (63% to 68%) by four to five months. Vaccine effectiveness of three doses against emergency department or urgent care visits was 83% (82% to 84%) initially but **waned to 46%** (44% to 49%) **by four to five months**. Waning was evident in all subgroups, including young adults and individuals who were not immunocompromised; although waning was more in people who were immunocompromised. Vaccine effectiveness increased among most groups after a fourth dose in whom this booster was recommended.

Conclusions: Effectiveness of mRNA vaccines against moderate and severe covid-19 waned with time after vaccination."

[489] **ADDED since 2/8/2022**

Increasing SARS-CoV2 cases, hospitalizations, and deaths among the vaccinated populations during the Omicron (B.1.1.529) variant surge in UK

Central Valley Cardiovascular Associates, California
Venkata R. Emani, Vivek K. Pallipuram, *et al*.
September 19, 2022
https://www.medrxiv.org/content/10.1101/2022.06.28.22276926v4.full-text

"**Results**: In summary, a significant decline in the risk of hospitalizations was observed both among the unvaccinated (1.27% vs 2.92%; RR 0.44 (0.42-0.45); p<0.001) and vaccinated (0.65% vs 1.19%; RR 0.54 (0.53-0.55); p<0.001) populations of over 18 years of age during the same period. We observed **negative vaccine effectiveness** (VE) for the third dose since December 20, 2021, with a significantly increased proportion of SARS-CoV2 cases hospitalizations, and deaths among the vaccinated; and a decreased proportion of cases, hospitalizations, and deaths among the unvaccinated. The pre-existing conditions were present in 95.6% of all COVID-19 deaths."

[490] **ADDED since 2/8/2022**

Vaccination against covid-19

Danish Health Authority
September 13, 2022
https://www.sst.dk/en/English/Corona-eng/Vaccination-against-COVID-19

"**Why are people aged under 50 not to be re-vaccinated?** …

The purpose of the vaccination programme is to prevent severe illness, hospitalisation and death. Therefore, people at the highest risk of becoming severely ill will be offered booster vaccination. The purpose of vaccination is **not** to prevent infection with covid-19, and people aged under 50 are therefore currently not being offered booster vaccination.

People aged under 50 are generally not at particularly higher risk of becoming severely ill from covid-19. In addition, younger people aged under 50 are well protected against becoming severely ill from covid-19, as a very large number of them have already been vaccinated and have previously been infected with covid-19, and there is consequently good immunity among this part of the population."

[491] **ADDED since 2/8/2022**

Effectiveness of 2, 3, and 4 COVID-19 mRNA Vaccine Doses Among Immunocompetent Adults During Periods when SARS-CoV-2 Omicron BA.1 and BA.2/BA.2.12.1 Sublineages Predominated — VISION Network, 10 States, December 2021–June 2022

Centers for Disease Control and Prevention
Ruth Link-Gelles, Matthew E. Levy, *et al*.
July 22, 2022
https://www.cdc.gov/mmwr/volumes/71/wr/mm7129e1.htm

"The Omicron variant (B.1.1.529) of SARS-CoV-2, the virus that causes COVID-19, was first identified in the United States in November 2021, with the BA.1 sublineage (including BA.1.1) causing the largest surge in COVID-19 cases to date. Omicron sublineages BA.2 and BA.2.12.1 emerged later and by late April 2022, accounted for most cases.* Estimates of COVID-19 vaccine effectiveness (VE) can be reduced by newly emerging variants or

sublineages that evade vaccine-induced immunity, protection from previous SARS-CoV-2 infection in unvaccinated persons, or increasing time since vaccination. Real-world data comparing VE during the periods when the BA.1 and BA.2/BA.2.12.1 predominated (BA.1 period and BA.2/BA.2.12.1 period, respectively) are limited. The VISION network† examined 214,487 emergency department/urgent care (ED/UC) visits and 58,782 hospitalizations with a COVID-19–like illness§ diagnosis among 10 states during December 18, 2021–June 10, 2022, to evaluate VE of 2, 3, and 4 doses of mRNA COVID-19 vaccines (BNT162b2 [Pfizer-BioNTech] or mRNA-1273 [Moderna]) compared with no vaccination among adults without immunocompromising conditions…

During the BA.1 period, VE declined to 73% ≥120 days (median = 132 days) after the third vaccine dose; during the BA.2/BA.12.1 period, **VE declined to 26% at ≥120 days** (median = 166 days) after the third dose."

[492] **ADDED since 2/8/2022**

Waning of SARS-CoV-2 vaccine-induced immunity: A systematic review and secondary data analysis

Bruno Kessler Foundation, Italy
Francesco Menegale, Mattia Manica, *et al*.
July 6, 2022
https://www.medrxiv.org/content/10.1101/2022.07.04.22277225v1.full-text

"**Introduction**: … In this study, we performed a systematic literature review of studies reporting VE at different time points since vaccine administration to estimate the waning of vaccine protection. We focused this review on the three most distributed COVID-19 vaccines in Western countries as of June 2022 [22]: BNT162b2 (Pfizer-BioNTech COVID-19 vaccine), mRNA-1273 (Moderna COVID-19 vaccine), and ChAdOx1 nCoV-19 (Oxford-AstraZeneca COVID-19 vaccine). We then performed a secondary analysis of the collected data to provide a cohesive picture of the waning rate associated with different vaccine products and quantified VE against SARS-CoV-2 infection and disease at any time from last dose administration, for different numbers of received doses, and different SARS-CoV-2 variants…

Discussion: … The performed analysis highlighted that the effectiveness of vaccination with 2 doses of BNT162b2, mRNA-1273, and ChAdOx1 nCoV-19 against any laboratory confirmed infection with Delta might have been lower than 70% at 9 months from last dose administration, and that the protection provided by a booster dose against Omicron infection rapidly wanes over time (31.5% mean VE at 6 months from administration). We found that the emergence of the Omicron variant reduced the initial effectiveness acquired from the primary vaccination course against symptomatic infection as well (from 76.2%-93.6% to 56.1%-83.6%, depending on the product considered), while increasing the pace of waning of protection. Our mean estimates indicated that at 6 months from the second dose, any considered vaccine has an effectiveness of **less than 13%** against Omicron symptomatic infection."

[493] **ADDED since 2/8/2022**

Dataset: Deaths occurring between 1 January 2021 and 31 May 2022 edition of this dataset
Office for National Statistics, UK
May 31, 2022
https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland
Direct link to Excel spreadsheet:
https://www.ons.gov.uk/file?uri=/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland/deathsoccurringbetween1january2021and31may2022/referencetable06072022accessible.xlsx
See also ***UK Gov. report admits 18.9 Million people still remain Unvaccinated in England & 50% of the country has refused the Booster but 90% of COVID Deaths since April were among the Triple Vaccinated***
https://expose-news.com/2022/07/16/19million-unvaccinated-england-90-percent-covid-deaths-triple-jabbed/

From the **Definitions** tab of spreadsheet:

> "For this analysis we define a death as involving COVID-19 if either of the ICD10 codes U07.1 (COVID-19, virus identified) or U07.2 (COVID-19, virus not identified) is mentioned on the death certificate. In contrast to the definition used in the weekly deaths released, deaths where the ICD10 code U09.9 (Post-COVID condition, where the acute COVID had ended before the condition immediately causing death occurred) is mentioned on the death certificate and neither of the other two COVID-19 codes are mentioned are not included, as they are likely to be the result of an infection caught a long time previously, and therefore not linked to the vaccination status of the person at date of death. Deaths involving U10.9 (Multisystem inflammatory syndrome associated with COVID-19) where neither U07.1 nor U07.2 are mentioned are also excluded."

"**Deaths Involving COVID-19**" for April and May of 2022, the most recent two months for which data is available as of 12/30/2022 (see screenshot below):

Unvaccinated:
288 (206 + 82)

Ever vaccinated:
4647 (3365 + 1282)

Third dose or booster, at least 21 days ago:
4114 (3057 + 1155)

	Cause of Death	Year	Month	Vaccination status	Count of deaths
293	Deaths involving COVID-19	2022	April	Unvaccinated	206
294	Deaths involving COVID-19	2022	April	First dose, less than 21 days ago	1
295	Deaths involving COVID-19	2022	April	First dose, at least 21 days ago	45
296	Deaths involving COVID-19	2022	April	Second dose, less than 21 days ago	0
297	Deaths involving COVID-19	2022	April	Second dose, between 21 days and 6 months ago	13
298	Deaths involving COVID-19	2022	April	Second dose, at least 6 months ago	246
299	Deaths involving COVID-19	2022	April	Third dose or booster, less than 21 days ago	3
300	Deaths involving COVID-19	2022	April	Third dose or booster, at least 21 days ago	3057
301	Deaths involving COVID-19	2022	April	Ever vaccinated	3365
302	Deaths involving COVID-19	2022	May	Unvaccinated	82
303	Deaths involving COVID-19	2022	May	First dose, less than 21 days ago	0
304	Deaths involving COVID-19	2022	May	First dose, at least 21 days ago	18
305	Deaths involving COVID-19	2022	May	Second dose, less than 21 days ago	0
306	Deaths involving COVID-19	2022	May	Second dose, between 21 days and 6 months ago	6
307	Deaths involving COVID-19	2022	May	Second dose, at least 6 months ago	103
308	Deaths involving COVID-19	2022	May	Third dose or booster, less than 21 days ago	0
309	Deaths involving COVID-19	2022	May	Third dose or booster, at least 21 days ago	1155
310	Deaths involving COVID-19	2022	May	Ever vaccinated	1282
311	Non-COVID-19 deaths	2021	January	Unvaccinated	28095
312	Non-COVID-19 deaths	2021	January	First dose, less than 21 days ago	5191
313	Non-COVID-19 deaths	2021	January	First dose, at least 21 days ago	1340

Cover | Contents | Definitions | Notes | **Table 1** | Table 2 | Table 3 | Table 4

[494] **ADDED since 2/8/2022**

Short term, relative effectiveness of four doses versus three doses of BNT162b2 vaccine in people aged 60 years and older in Israel: retrospective, test negative, case-control study

British Medical Journal — Maccabi Healthcare Services, Israel
Sivan Gazit, Yaki Saciuk, *et al*.
May 24, 2022
https://www.bmj.com/content/377/bmj-2022-071113

"**Objective**: To examine the relative effectiveness of a fourth dose of the Pfizer-BioNTech mRNA (BNT162b2) vaccine compared with three vaccine doses over the span of 10 weeks…

Results: 27 876 participants received the fourth BNT162b2 vaccine dose and 69 623 received three doses only. Of 106 participants who died during the follow-up period, 77 had had their third doses only and 23 had had their fourth doses during the first three weeks after inoculation. In the first three weeks, a fourth dose provided additional protection against both SARS-CoV-2 infection and severe disease relative to three doses of the vaccine. However, relative vaccine effectiveness against infection quickly decreased over time, peaking during the third week at 65.1% (95% confidence interval 63.0% to 67.1%) and **falling to 22.0%** (4.9% to 36.1%) by the end of the 10 week follow-up period."

[495] **ADDED since 2/8/2022**

Research Letter: *Routine Surveillance and Vaccination on a University Campus During the Spread of the SARS-CoV-2 Omicron Variant*

JAMA Network Open — Cornell University
Genevive Meredith, Diego G. Diel, *et al*.
May 18, 2022
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2792382

"**Results**: From November 28 to December 31, 2797 COVID-19 cases were identified (mean [SD], 82.3 [82.4] cases/d; 3.1% positivity; 89.0% students, 11.0% employees), eclipsing previously measured incidence. Most cases (82.2%) reported mild symptoms (no reported hospitalizations). Despite high vaccination rates (97.9% of campus3), **98.6% of cases were breakthrough infections**…

Discussion: The Omicron variant is highly transmissible, particularly in high-density social settings.5,6 Based on analysis of routinely collected population surveillance data, Cornell's experience shows that traditional public health interventions were not a match for Omicron. While vaccination protected against severe illness, it was not sufficient to prevent rapid spread, even when combined with other public health measures including widespread surveillance testing."

[496] **ADDED since 2/8/2022**

Association of Prior BNT162b2 COVID-19 Vaccination With Symptomatic SARS-CoV-2 Infection in Children and Adolescents During Omicron Predominance

JAMA — US Centers for Disease Control and Prevention
Katherine E. Fleming-Dutra, Amadea Britton, *et al*.
May 13, 2022
https://jamanetwork.com/journals/jama/fullarticle/2792524

"**Question**: Does the estimated effectiveness of 2 doses of the BNT162b2 COVID-19 vaccine against symptomatic SARS-CoV-2 Omicron variant infection (based on the odds ratio for the association of prior vaccination and infection) wane rapidly among children and adolescents, as has been observed for adults?

Findings: In a test-negative, case-control study conducted from December 2021 to February 2022 during Omicron variant predominance that included 121,952 tests from sites across the US, estimated vaccine effectiveness against symptomatic infection for children 5 to 11 years of age was 60.1% 2 to 4 weeks after dose 2 and **28.9% during month 2 after dose 2**. Among adolescents 12 to 15 years of age, estimated vaccine effectiveness was 59.5% 2 to 4 weeks after dose 2 and **16.6% during month 2**; estimated booster dose effectiveness in adolescents 2 to 6.5 weeks after the booster was 71.1%.

Meaning: Among children and adolescents, estimated vaccine effectiveness for 2 doses of BNT162b2 against symptomatic infection decreased rapidly, and among adolescents increased after a booster dose…

Results: … For adolescents 12 to 15 years old, the adjusted OR [*odds ratio*] during month 0 after the second dose was 0.40 (95% CI, 0.29-0.56; estimated VE [*vaccine effectiveness*], 59.5% [95% CI, 44.3%-70.6%]), during month 2 after the second dose was 0.83 (95% CI, 0.76-0.92; estimated VE, 16.6% [95% CI, 8.1%-24.3%]), and was **no longer significantly different from 0** during month 3 after the second dose (OR, 0.90 [95% CI, 0.82-1.00]"

[497] **ADDED since 2/8/2022**

Protection by a Fourth Dose of BNT162b2 against Omicron in Israel

New England Journal of Medicine
Yinon M. Bar-On, Yair Goldberg, *et al*.
May 5, 2022
https://www.nejm.org/doi/full/10.1056/NEJMoa2201570

"**Discussion**: The omicron variant is genetically divergent from the ancestral SARS-CoV-2 strain for which the BNT162b2 vaccine was tailored. The results presented here indicate that as compared with three vaccine doses given at least 4 months earlier, a fourth dose provides added short-term protection against confirmed infections and severe illness caused by the omicron variant. The incidence rate for confirmed infection was lower by a factor of 2 and the rate of severe disease lower by a factor of 3 among persons in the fourth week after receiving the fourth dose than among eligible persons who did not receive the fourth dose.

Comparing the rate ratio over time since the fourth dose (Figure 2) suggests that the protection against confirmed infection with the omicron variant **reaches a maximum in the fourth week** after vaccination, after which the rate ratio decreases to approximately **1.1 by the eighth week**; these findings suggest that protection against confirmed infection wanes

quickly. In contrast, protection against severe illness did not appear to decrease by the sixth week after receipt of the fourth dose."

[498] **ADDED since 2/8/2022**

COVID-19 vaccine surveillance report, Week 13

UK Health Security Agency

March 31, 2022

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1066759/Vaccine-surveillance-report-week-13.pdf

Note: This is the last surveillance report with the tables below indicating vaccination status for COVID-19 emergency-care admissions and deaths. Subsequent reports through the end of 2022 do not provide this information.

"**From Table 12 (below)**: COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission between week 9 2022 and week 12 2022:

- 10,389 Total (100%)
- 2,065 Not vaccinated (19.9% of Total)
- **7,930** Second dose > or = 14 days before specimen date **or** Third dose > or = 14 days before specimen date (**76.3%** of Total)

Table 12. COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 9 2022 and week 12 2022

Please note that corresponding rates by vaccination status can be found in Table 14.

Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between week 9 2022 (w/e 6 March 2022) and week 12 2022 (w/e 27 March 2022)	Total	Unlinked*	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]	Third dose ≥14 days before specimen date[1]
	[This data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]						
Under 18	1,096	27	965	5	56	38	5
18 to 29	690	8	246	3	47	190	196
30 to 39	692	5	200	0	38	156	293
40 to 49	582	10	124	0	34	111	303
50 to 59	892	1	127	1	37	155	571
60 to 69	1,054	5	116	0	24	135	774
70 to 79	2,014	5	140	1	29	171	1,668
80 or over	3,369	2	147	1	55	224	2,940

* Individuals whose NHS numbers were unavailable to link to the NIMS.

[1] In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19.

From Table 13 (below): COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, between week 9 2022 and week 12 2022:

- 2,144 Total (100%)
- 214 Not vaccinated (10.0% of Total)
- **1,871** Second dose > or = 14 days before specimen date **or** Third dose > or = 14 days before specimen date (**87.3%** of Total)

Table 13. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 9 2022 and week 12 2022
Please note that corresponding rates by vaccination status can be found in Table 14.
(a)

Death within 28 days of positive COVID-19 test by date of death between week 9 2022 (w/e 6 March 2022) and week 12 2022 (w/e 27 March 2022)	Total**	Unlinked*	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]	Third dose ≥14 days before specimen date[1]
	[This data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]						
Under 18	2	0	1	0	1	0	0
18 to 29	6	0	1	0	0	1	4
30 to 39	20	0	8	0	1	3	8
40 to 49	26	1	5	0	1	9	10
50 to 59	72	0	16	0	5	17	34
60 to 69	163	1	31	0	11	39	81
70 to 79	435	3	48	0	6	70	308
80 or over	1,420	5	104	1	23	175	1,112

* Individuals whose NHS numbers were unavailable to link to the NIMS.
** number of deaths of people who had had a positive test result for COVID-19 and either died within 60 days of the first positive test or have COVID-19 mentioned on their death certificate.
[1] In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19.

[499] **ADDED since 2/8/2022**
Effectiveness of mRNA vaccines and waning of protection against SARS-CoV-2 infection and severe covid-19 during predominant circulation of the delta variant in Italy: retrospective cohort study
British Medical Journal — Italian National Institute of Health
Massimo Fabiani, Maria Puopolo, *et al*.
February 10, 2022
https://www.bmj.com/content/376/bmj-2021-069052

"**Objectives** To estimate the effectiveness of mRNA vaccines against SARS-CoV-2 infection and severe covid-19 at different time after vaccination…

Results: During the epidemic phase when the delta variant was the predominant strain of the SARS-CoV-2 virus, vaccine effectiveness against SARS-CoV-2 infection **significantly decreased** (P<0.001) from 82% (95% confidence interval 80% to 84%) at 3-4 weeks after the second dose of vaccine to 33% (27% to 39%) at 27-30 weeks after the second dose. In the same time intervals, vaccine effectiveness against severe covid-19 also decreased (P<0.001), although to a lesser extent, from 96% (95% to 97%) to 80% (76% to 83%). High risk people (vaccine effectiveness −6%, −28% to 12%), those aged ≥80 years (11%, −15% to 31%), and those aged 60-79 years (2%, −11% to 14%) **did not seem to be protected against infection** at 27-30 weeks after the second dose of vaccine."

[500] **ADDED since 2/8/2022**
'80% of serious COVID cases are fully vaccinated' says Ichilov hospital director
Israel National News
February 3, 2022
https://www.israelnationalnews.com/news/321674

"Prof. Jacob Giris, director of Ichilov Hospital's coronavirus ward, said in a TV interview that many of the severe cases are vaccinated.

'Right now, most of our severe cases are vaccinated,' Giris told Channel 13 News. 'They had at least three injections. **Between seventy and eighty percent of the serious cases are vaccinated**. So, the vaccine has no significance regarding severe illness, which is why just twenty to twenty-five percent of our patients are unvaccinated.'

Giris also spoke at the cabinet meeting on Sunday and told ministers, 'Defining a serious patient is problematic. For example, a patient with a chronic lung disease always had a low level of oxygen, but now he has a positive coronavirus test result which technically makes him a 'serious coronavirus patient,' but that's not accurate. The patient is only in a difficult condition because he has a serious underlying illness.'"

[501] ***COVID-19 vaccine surveillance report, Week 5***
UK Health Security Agency
February 3, 2022
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1052353/Vaccine_surveillance_report_-_week_5.pdf

"**From Table 11 (below)**: COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission between week 52 2021 and week 3 2022:

- 16,294 Total (100%)
- 4,807 Not vaccinated (29.5%)
- **10,448** Second dose > or = 14 days before specimen date **or** Third dose > or = 14 days before specimen date (**64.1%**)

Table 11. COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 52 2021 and week 3 2022

Please note that corresponding rates by vaccination status can be found in Table 13. Please be aware that this data was not updated for the week 5 report.

Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between week 52 2021 (w/e 02/01/2022) and week 3 2022 (w/e 23/01/2022)	Total	Unlinked*	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]	Third dose ≥14 days before specimen date[1]
	[This data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]						
Under 18	1,835	85	1,597	10	118	21	4
18 to 29	1,445	32	522	10	140	580	161
30 to 39	1,395	11	546	9	105	513	211
40 to 49	1,349	27	389	7	92	482	352
50 to 59	1,696	17	461	10	76	530	602
60 to 69	1,866	21	446	13	66	480	840
70 to 79	2,683	11	411	6	68	576	1,611
80 or over	4,025	6	435	3	96	817	2,668

* Individuals whose NHS numbers were unavailable to link to the NIMS.
[1] In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19.

From Table 12 (below): COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, between week 1 2022 and week 4 2022:

- 5,554 Total (100%)
- 1,015 Not vaccinated (18.3%)
- **4,288** Second dose > or = 14 days before specimen date **or** Third dose > or = 14 days before specimen date (**77.2%**)

Table 12. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 1 2022 and week 4 2022
Please note that corresponding rates by vaccination status can be found in Table 13.
(a)

Death within 28 days of positive COVID-19 test by date of death between week 1 2022 (w/e 09/01/2022) and week 4 2022 (w/e 30/01/2022)	Total**	Unlinked*	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]	Third dose ≥14 days before specimen date[1]
	[This data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]						
Under 18	12	0	8	0	2	2	0
18 to 29	31	1	16	0	1	9	4
30 to 39	76	0	30	0	6	30	10
40 to 49	125	1	49	0	13	38	24
50 to 59	311	4	106	0	21	115	65
60 to 69	642	12	192	1	21	227	189
70 to 79	1220	4	241	3	51	372	549
80 or over	3,137	16	373	5	89	910	1,744

* Individuals whose NHS numbers were unavailable to link to the NIMS.
** number of deaths of people who had had a positive test result for COVID-19 and either died within 60 days of the first positive test or have COVID-19 mentioned on their death certificate.
[1] In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19.

[502] **ADDED since 2/8/2022**

Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study

The Lancet — Imperial College London
Anika Singanayagam, Seran Hakki, *et al*.
February 2022
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8554486/

"**Background**: The SARS-CoV-2 delta (B.1.617.2) variant is highly transmissible and spreading globally, including in populations with high vaccination rates. We aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community…

Methods: … Primary outcomes for the epidemiological analysis were to assess the secondary attack rate (SAR) in household contacts stratified by contact vaccination status and the index cases' vaccination status. Primary outcomes for the viral load kinetics analysis were to detect differences in the peak viral load, viral growth rate, and viral decline rate between participants according to SARS-CoV-2 variant and vaccination status…

Findings: SAR among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% [95% CI 15–35] for vaccinated vs 23% [15–31] for unvaccinated). 12 (39%) of 31 infections in fully vaccinated household contacts arose from fully vaccinated epidemiologically linked index cases, further confirmed by genomic and virological analysis in three index case–contact pairs. Although peak viral load did not differ by vaccination status or variant type, it increased modestly with age…

Interpretation: … [F]ully vaccinated individuals with breakthrough infections have **peak viral load similar to unvaccinated cases** and **can efficiently transmit infection in household settings, including to fully vaccinated contacts**."

[503] ***COVID-19 in Northern Ireland: Vaccination Status of Deaths and Hospitalisations — Updated to Include Weeks 51 to 2 (20th December 2021 to 16th January 2022)***

Roinn Sláinte, Department of Health
January 2022
https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-vaccination-status-weeks-51-02.pdf

"**Methods**: … A person is deemed vaccinated if the date of vaccination is greater than or equal to 14 days before date of admission, or for deaths, if the date of vaccination is greater than or equal to 14 days before date of specimen."

Note: According to Table 1b below, between December 20 2021 and January 16 2022:

- Unvaccinated COVID-19 cases had a hospital admission rate of **190.3** per 100,000.
- COVID-19 cases with one or more shots had a hospital admission rate of **178.7** per 100,000 (110.0 + 23.4 + 45.3).

According to Table 2b below, between December 20 2021 and January 16 2022:

- Unvaccinated COVID-19 cases had a death rate of **18.0** per 100,000.
- COVID-19 cases with one or more shots had a death rate of **13.9** per 100,000 (9.0 + 4.9).

Table 1b: COVID-19 cases admitted to hospital between 20th December 2021 and 16th January 2022

Age Cohort	Not Vaccinated	Missing	Partially Vaccinated (1 dose)	Fully Vaccinated (2 doses)	Fully Vaccinated + Booster or Dose 3	Total Admissions	Rates Admitted to Hospital per 100,000			
							Not Vaccinated	Partially Vaccinated	Fully Vaccinated (2 doses)	Fully Vaccinated + Booster or Dose 3
Under 18	41	0	3	2	0	46	11.5	4.9	8.4	0.0
18-29	37	0	4	38	4	83	72.8	25.9	18.6	8.8
30-39	41	1	5	34	7	88	102.9	45.9	16.9	9.7
40-49	45	0	7	25	16	93	224.3	116.0	11.7	14.2
50-59	42	1	5	46	30	124	352.5	122.9	19.0	17.0
60-69	51	4	8	30	53	146	823.0	304.0	15.3	32.3
70-79	25	4	6	56	87	178	514.9	248.1	39.3	67.3
80+	24	0	14	70	150	258	418.0	475.4	93.0	228.5
Adults Under 50	123	1	16	97	27	264	111.1	49.4	15.7	11.7
50 & Over	142	9	33	202	320	706	494.6	273.5	30.8	59.8
All Adults	265	10	49	299	347	970	190.3	110.0	23.4	45.3

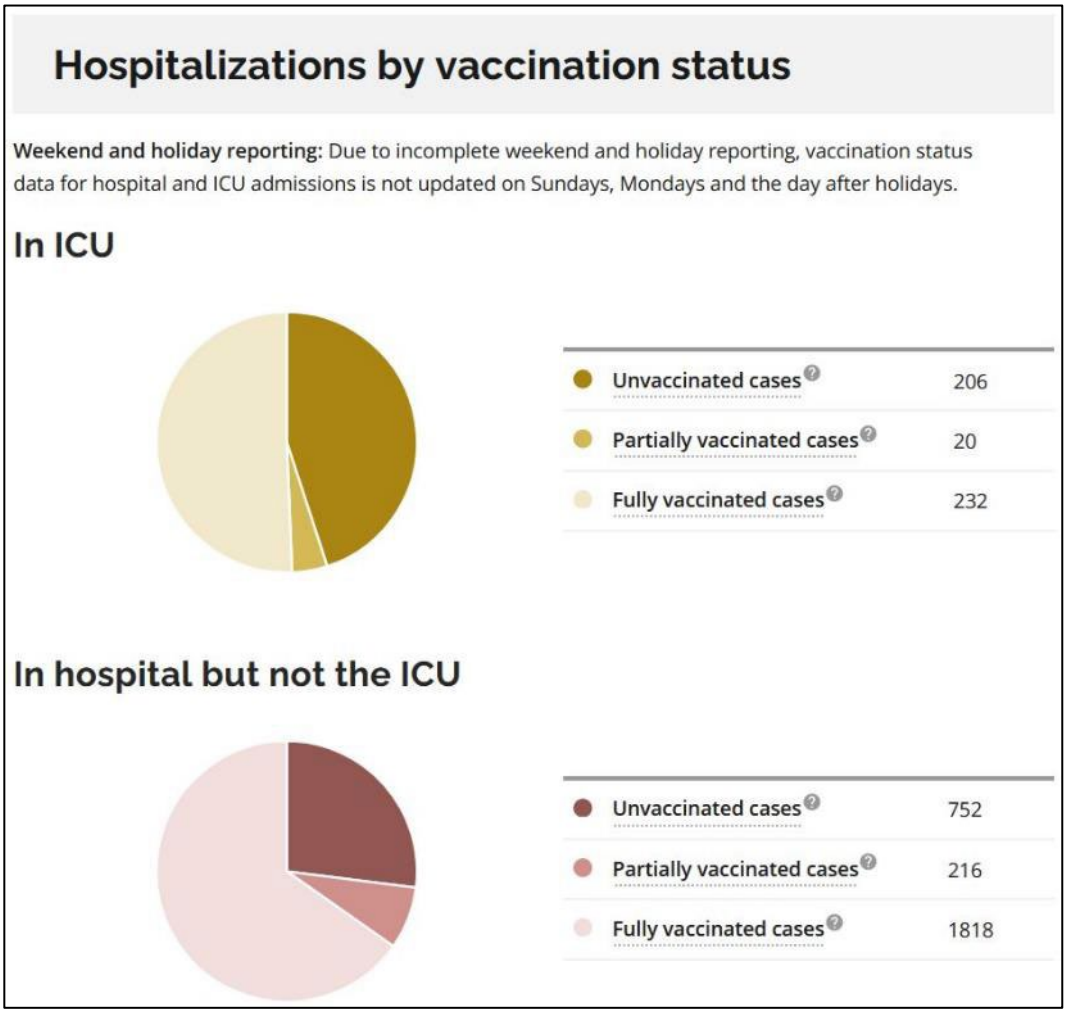
Table 2b: COVID-19 deaths within 28 days of a positive test between 20th December 2021 and 16th January 2022

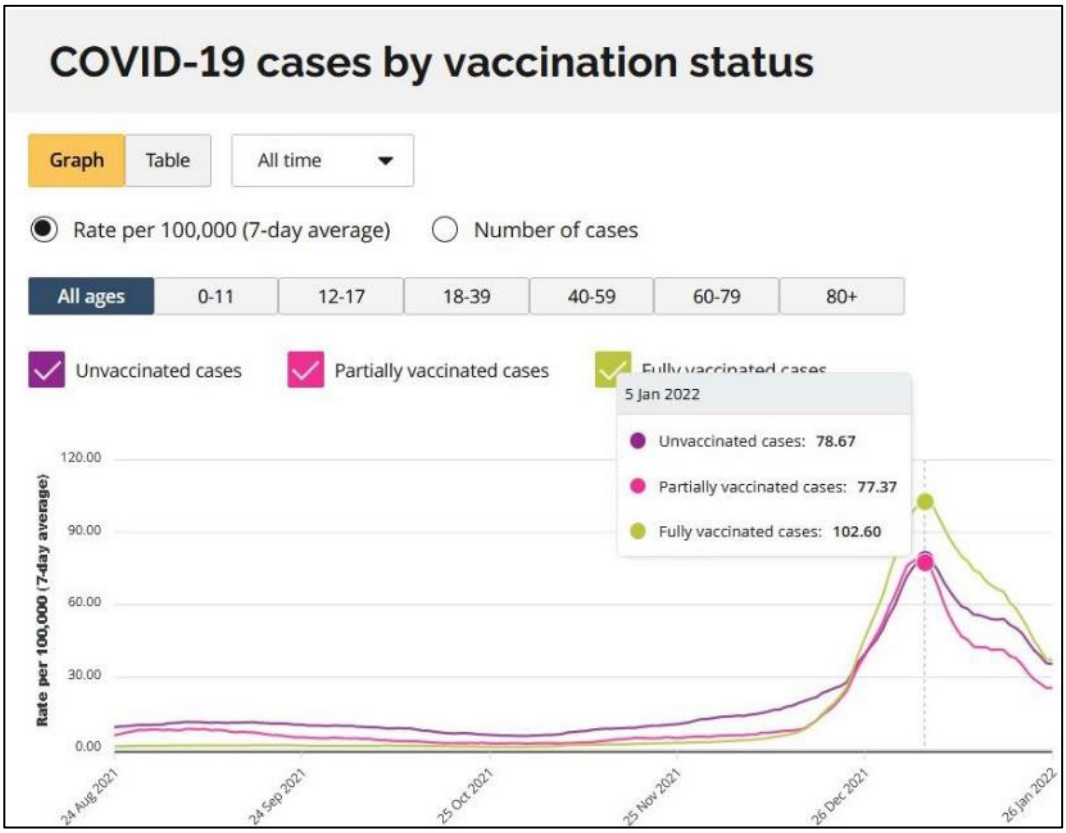
Age Cohort	Not Vaccinated	Missing	Partially Vaccinated	Fully Vaccinated (at least 2 doses)	Total Deaths	Death Rates per 100,000		
						Not Vaccinated	Partially Vaccinated	Fully Vaccinated (at least 2 doses)
Adults Under 50	3	0	0	0	3	2.7	0.0	0.0
50-59	3	0	1	3	7	25.2	24.6	1.2
60-69	9	0	0	9	18	145.2	0.0	4.6
70-79	3	0	0	25	28	61.8	0.0	17.6
80+	7	0	3	26	36	121.9	101.9	34.5
50 & Over	22	0	4	63	89	76.6	33.2	9.6
All Adults	25	0	4	63	92	18.0	9.0	4.9

* Age cohorts below 50 are not provided to avoid potential disclosure of individual details.

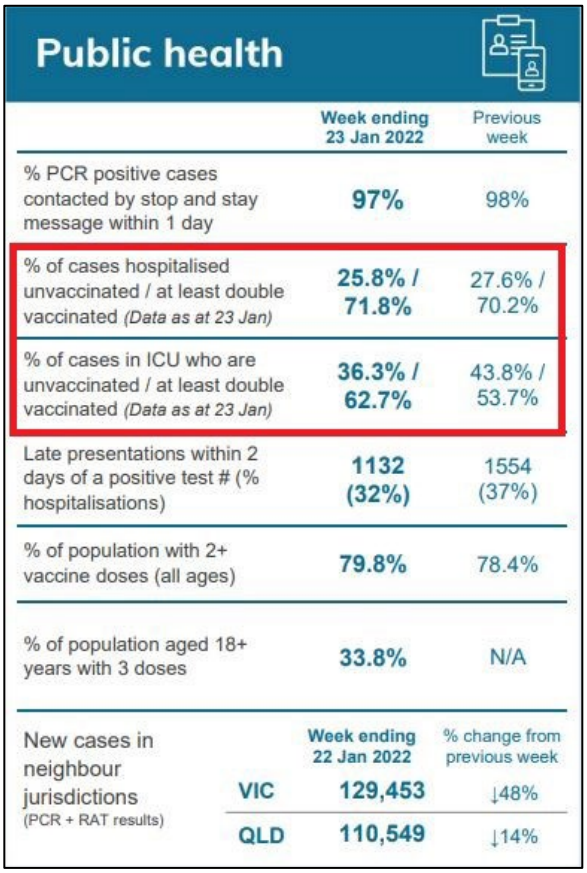
[504] ***COVID-19 vaccinations data***
Government of Ontario
Last updated January 26, 2022
https://covid-19.ontario.ca/data

Note: In the chart below, the "Unvaccinated" include "cases where people did not have any vaccine dose, **or** where symptoms started between 0 and less than 14 days after receiving the first dose of a COVID-19 vaccine."




COVID-19 cases by vaccination status
Graph
Table
All time
Rate per 100,000 (7-day average)
Number of cases
All ages
0-11
12-17
18-39
40-59
60-79
80+
Unvaccinated cases
Partially vaccinated cases
5 Jan 2022
Unvaccinated cases: 78.67
Partially vaccinated cases: 77.37
Fully vaccinated cases: 102.60
Rate per 100,000 (7-day average)
120.00
90.00
60.00
30.00
0.00
24 Aug 2021
24 Sep 2021
25 Oct 2021
25 Nov 2021
26 Dec 2021
26 Jan 2022

[505] ***COVID-19 Risk Monitoring Dashboard – Healthcare settings***
New South Wales Ministry of Health
January 25, 2022
https://aci.health.nsw.gov.au/__data/assets/pdf_file/0012/700032/20220125-COVID-19-Risk-Monitoring-Dashboard.pdf



Public health

	Week ending 23 Jan 2022	Previous week
% PCR positive cases contacted by stop and stay message within 1 day	**97%**	98%
% of cases hospitalised unvaccinated / at least double vaccinated *(Data as at 23 Jan)*	**25.8% / 71.8%**	27.6% / 70.2%
% of cases in ICU who are unvaccinated / at least double vaccinated *(Data as at 23 Jan)*	**36.3% / 62.7%**	43.8% / 53.7%
Late presentations within 2 days of a positive test # (% hospitalisations)	**1132 (32%)**	1554 (37%)
% of population with 2+ vaccine doses (all ages)	**79.8%**	78.4%
% of population aged 18+ years with 3 doses	**33.8%**	N/A

New cases in neighbour jurisdictions (PCR + RAT results)		Week ending 22 Jan 2022	% change from previous week
	VIC	**129,453**	↓48%
	QLD	**110,549**	↓14%

[506] ***Prof. Eran Segal: Decrease in Omicron cases expected later this week***
Jerusalem Post
Shira Silkoff, Jerusalem Post Staff
January 21, 2022
https://www.jpost.com/breaking-news/article-694179

> "There are currently 453,505 active coronavirus cases in Israel, 452,692 of which (99.8%) are classified as mild. A total of 219,646 people are currently self-isolating.
>
> As of Friday, **55% of serious cases were in patients who had received three vaccines**, and 24% had not been vaccinated at all [*emphasis added*]."

[507] ***Public Health Scotland COVID-19 Statistical Report As at 17 January 2022***
Public Health Scotland
January 19, 2022
https://www.publichealthscotland.scot/media/11223/22-01-19-covid19-winter_publication_report.pdf

Notes: Per Table 11 (below), from December 11th 2021 through January 7th 2022, Public Health Scotland identified 288,266 **COVID-19 cases**. Of this number, 42,565 (14.8%) were unvaccinated and 245,701 (85.2%) had received at least one dose.

Average Age Standardized Case Rate for each group per 100,000 people:

- Unvaccinated = 885; i.e., [(482.87 + 721.39 + 1242.10 + 1092.80) / 4]
- One Dose = 1,189, i.e., [(574.16 + 958.62 + 1693.71 + 1527.57) / 4]
- Two Doses = 1,938; i.e., [(826.49 + 1527.87 + 2897.58 + 2499.52) / 4]
- Three Doses = 1,146; i.e., [(458.39 + 902.02 + 1755.69 + 1466.76) / 4]

Table 11: Age-standardised case rate per 100,000 individuals by week and vaccination status, 11 December 2021 to 07 January 2022

	Unvaccinated		1 Dose	
Week	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	6,545	**482.87** (464.41 - 501.34)	2,952	**574.16** (538.46 - 609.85)
18 December - 24 December 2021	9,070	**721.39** (698.44 - 744.34)	4,639	**958.62** (911.03 - 1,006.20)
25 December - 31 December 2021	14,465	**1,242.10** (1,209.27 - 1,274.94)	7,657	**1,693.71** (1,631.31 - 1,756.11)
01 January 2022 – 07 January 2022	12,485	**1,092.80** (1,063.90 - 1,121.71)	6,702	**1,527.57** (1,462.52 - 1,592.63)
	2 Doses		Booster or 3rd Dose	
Week	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	20,788	**826.49** (809.83 - 843.16)	3,926	**458.39** (400.49 - 516.29)
18 December - 24 December 2021	35,123	**1,527.87** (1,501.86 - 1,553.88)	10,193	**902.02** (841.06 - 962.98)
25 December - 31 December 2021	54,860	**2,897.58** (2,859.92 - 2,935.23)	30,327	**1,755.69** (1,701.98 - 1,809.40)
01 January 2022 – 07 January 2022	35,119	**2,499.52** (2,462.50 - 2,536.53)	33,415	**1,466.76** (1,418.18 - 1,515.33)

Date are only based on PCR results. Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 6. The data displayed within the greyed-out section are considered preliminary and are subject to change as more data is updated. Age-standardised case rates are per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 6). On average, unvaccinated individuals are younger than individuals with two or more doses of COVID-19 vaccine. To compare across vaccination statuses (unvaccinated, 1 dose, 2 doses or booster/3 doses), age-standardised case rates are calculated to adjust for differences in age distribution. COVID-19 cases included in this table for the *age-standardised rates only includes individuals 10 years old and over. Although the majority of 10 and 11 year olds are currently not eligible for vaccination, the five-year age band standardised to the 2013 European Standard Population used in this analysis ranges from 10-14 years and therefore cases and denominators for these age groups are included.*

Per Table 12 (below), from December 11th 2021 through January 7th 2022, Public Health Scotland identified 2,193 **COVID-19 hospitalizations**. Of this number, 545 (24.9%) were unvaccinated and 1,648 (75.1%) had received at least one dose.

Average Age Standardized Hospitalization Rate for each group per 100,000 people:

- Unvaccinated = 63; i.e., [(43.94 + 64.55 + 84.17 + 59.17) / 4]
- One Dose = 42, i.e., [(37.48 + 14.06 + 53.62 + 63.78) / 4]
- Two Doses = 75, i.e., [(46.46 + 45.21 + 78.91 + 130.14) / 4]
- Three Doses = 12, i.e., [(4.29 + 6.94 + 20.54 + 14.82) / 4]

Table 12: Age-standardised rate of acute hospital admissions where an individual had a COVID-19 positive PCR test up to 14 days prior, on admission, or during their stay in hospital, by week and vaccination status, 11 December 2021 to 07 January 2022

	Unvaccinated		1 Dose	
Week	No. hospitalised	Age Standardised hospitalisation Rate per 100,000 with 95% confidence intervals	No. hospitalised	Age Standardised hospitalisation Rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	98	**43.94** (24.34 - 63.54)	20	**37.48** (8.44 - 66.53)
18 December - 24 December 2021	134	**64.55** (38.00 - 91.11)	14	**14.06** (-4.71 - 32.83)
25 December - 31 December 2021	168	**84.17** (56.69 - 111.65)	43	**53.62** (19.11 - 88.12)
01 January 2022 – 07 January 2022	145	**59.17** (26.42 - 91.92)	46	**63.78** (12.51 - 115.04)
	2 Doses		Booster or 3rd Dose	
Week	No. hospitalised	Age Standardised hospitalisation Rate per 100,000 with 95% confidence intervals	No. hospitalised	Age Standardised hospitalisation Rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	189	**46.46** (25.71 - 67.21)	75	**4.29** (3.07 - 5.50)
18 December - 24 December 2021	165	**45.21** (32.10 - 58.33)	116	**6.94** (5.36 - 8.53)
25 December - 31 December 2021	225	**78.91** (58.05 - 99.76)	273	**20.54** (15.80 - 25.28)
01 January 2022 – 07 January 2022	184	**130.14** (81.50 - 178.79)	298	**14.82** (12.12 - 17.53)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 6. The data displayed within the greyed-out section are considered preliminary and are subject to change as more data is updated. Age-standardised hospitalisation rates are per 100,000 people per week, standardised to the 2013 European Standard Population adjusted to only include individuals 16 years old and over (see Appendix 6).

Per Table 13 (below), from December 11th 2021 through January 7th 2022, Public Health Scotland identified 240 **COVID-19 related deaths**. Of this number, 46 (19.2%) were unvaccinated and 194 (80.1%) had received at least one dose.

Average Age Standardized Mortality Rate for each group per 100,000 people:

- Unvaccinated = 4.8; i.e., [(5.56 + 7.13 + 1.72 + 4.79) / 4]
- One Dose = 9.2, i.e., [(17.24 + 3.93 + 15.27 + 0.36) / 4]
- Two Doses = 7.7, i.e., [(9.44 + 7.66 + 6.52 + 7.06) / 4]
- Three Doses = 0.3, i.e., [(0.26 + 0.20 + 0.33 + 0.21) / 4]

Table 13: Number of confirmed COVID-19 related deaths by vaccination status at time of test and age-standardised mortality rate per 100,000, 04 December 2021 to 31 December 2021

	Unvaccinated		1 Dose	
Week	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
04 December - 10 December 2021	14	**5.56** (1.60 - 9.53)	6	**17.24** (3.36 - 31.12)
11 December - 17 December 2021	18	**7.13** (2.68 - 11.58)	3	**3.93** (0.00 - 9.22)
18 December - 24 December 2021	6	**1.72** (0.22 - 3.22)	7	**15.27** (2.87 - 27.66)
25 December - 31 December 2021	8	**4.79** (0.58 - 8.99)	1	**0.36** (0.00 - 1.05)
	2 Doses		Booster or 3rd Dose	
Week	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
04 December - 10 December 2021	56	**9.44** (6.78 - 12.10)	8	**0.26** (0.05 - 0.46)
11 December - 17 December 2021	36	**7.66** (5.03 - 10.28)	8	**0.20** (0.06 - 0.33)
18 December - 24 December 2021	24	**6.52** (3.78 - 9.25)	15	**0.33** (0.16 - 0.49)
25 December - 31 December 2021	21	**7.06** (3.82 - 10.30)	9	**0.21** (0.07 - 0.34)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 6. A confirmed COVID-19 related death is defined as an individual who has tested positive by PCR for SARS-CoV-2 at any time point and has COVID-19 listed as an underlying or contributory cause of death on the death certificate. Age-standardised mortality rates per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 6). This definition is for the purposes of evaluating the impact of the COVID-19 vaccine on confirmed COVID-19 deaths. The numbers reported in this section may differ from other published COVID-19 death data. Data are based on date of registration. In Scotland deaths must be registered within 8 days although in practice, the average time between death and registration is around 3 days. More information on days between occurrence and registration can be found on the NRS website.

[508] **Video (3m starting at 32:30): WHO media briefing on COVID-19**
World Health Organization
Comments by Dr. Soumya Swaminathan, WHO Chief Scientist
January 18, 2022
https://www.youtube.com/watch?v=oIa0hAimtfU

Swaminathan (32:30m) : "Against Omicron, many of the vaccines have shown a reduction in efficacy against infection, and that's why we see a lot of breakthrough infections…

There's **no evidence** right now that healthy children or healthy adolescents need boosters. No evidence at all."

[509] ***Israeli trial, world's first, finds 4th dose 'not good enough' against Omicron***
The Times of Israel
TOI Staff
January 18, 2022
https://www.timesofisrael.com/israeli-trial-worlds-first-finds-4th-dose-not-good-enough-against-omicron/

"Nearly a month after Sheba Medical Center launched a landmark study to test the efficacy of a fourth COVID shot, the hospital said Monday that this fourth booster was only partially effective in protecting against the Omicron strain.

'The vaccine, which was very effective against the previous strains, is less effective against the Omicron strain,' Prof. Gili Regev-Yochay, a lead researcher in the experiment said.

'We see an increase in antibodies, higher than after the third dose,' Regev-Yochay said. 'However, we see many infected with Omicron who received the fourth dose. Granted, a bit less than in the control group, but still a lot of infections,' she added."

[510] **Video (30m) - *Israeli vaccine advisor: "We have made mistakes."***
UnHerd
Interview with Professor Cyrille Cohen, head of Immunology at Bar Ilan University and a member of the advisory committee for vaccines for the Israeli Government
January 18, 2022
https://unherd.com/thepost/israeli-vaccine-chief-we-have-made-mistakes/

Cohen: "So we did believe at that time [*spring 2021*] that the vaccines can prevent also transmission. And the data was also in that sense, what we believed is, you know, vaccines can prevent transmission perhaps shortly after they've been administered, but not over a long period of time. And, therefore, yes, we were surprised to discover, at the end of the day, that no, **the vaccines are not protecting us**, **are not causing what we call 'sterilizing immunity'** [*emphasis added*]."

[511] ***COVID-19 Monitor: COVID-19 cases, variants, vaccines, hospitalisations and deaths***
New South Wales Agency for Clinical Innovation (Australia)
January 13, 2022
https://aci.health.nsw.gov.au/__data/assets/pdf_file/0008/698804/20220113-COVID-19-Monitor.pdf

From Table 1 on page 1:

COVID-19 patients in hospital, as at 9 Jan: 2,030

- Percentage who were unvaccinated: 28.8%
- Percentage who were double vaccinated: 68.9%

COVID-19 patients in intensive care units (ICUs), as at 9 Jan: 159

- Percentage who were unvaccinated: 49.1%
- Percentage who were double vaccinated: 50.3%

[512] ***COVID-19 Weekly Surveillance in NSW: Epidemiological Week 52 ending 1 January 2022***
New South Wales Ministry of Health
January 13, 2022
https://www.health.nsw.gov.au/Infectious/covid-19/Documents/covid-19-surveillance-report-20220113.pdf

Table 5. Demographics of confirmed and probable Omicron infections, Delta infections, and infections without genomic sequencing by gender, age, vaccination status and clinical severity, NSW, 26 November 2021 to 1 January 2022

	Confirmed Omicron Cases	Probable Omicron Cases^	Confirmed Delta Cases	Not Sequenced
Gender				
Female	736 (51%)	1,473 (50%)	1,242 (47%)	73,153 (50%)
Male	709 (49%)	1,442 (49%)	1,374 (52%)	72,017 (50%)
Not stated	4 (<1%)	9 (<1%)	6 (<1%)	275 (<1%)
Age group*				
0-9	33 (2%)	83 (3%)	378 (14%)	9,149 (6%)
10-19	249 (17%)	516 (18%)	461 (18%)	19,518 (13%)
20-29	654 (45%)	1,446 (49%)	586 (22%)	45,449 (31%)
30-39	178 (12%)	442 (15%)	410 (16%)	27,916 (19%)
40-49	122 (8%)	202 (7%)	325 (12%)	17,371 (12%)
50-59	89 (6%)	145 (5%)	196 (7%)	13,892 (10%)
60-69	44 (3%)	56 (2%)	140 (5%)	7,424 (5%)
70-79	38 (3%)	21 (1%)	83 (3%)	3,207 (2%)
80-89	33 (2%)	12 (<1%)	37 (1%)	1,194 (1%)
90+	9 (1%)	1 (<1%)	6 (<1%)	312 (<1%)
Vaccination status				
Fully vaccinated	1,152 (80%)	2,349 (80%)	1,268 (48%)	103,289 (71%)
Partially vaccinated	15 (1%)	9 (0%)	47 (2%)	1,041 (1%)
No effective dose	32 (2%)	44 (2%)	450 (17%)	2,240 (2%)
Under investigation#	209 (14%)	425 (15%)	327 (12%)	27,215 (19%)
Not eligible (aged 0-11 years)	41 (3%)	97 (3%)	530 (20%)	11,660 (8%)

Table 6. Hospitalisations, ICU admissions and deaths among cases diagnosed with COVID-19, by vaccination status, NSW, from 26 November 2021 to 1 January 2022

Vaccination status	Total cases	Hospitalised (% of total cases)	Hospitalised and in ICU (% of total cases)	Death (% of total cases)
Fully vaccinated	108,056	1,280 (1.2%)	104 (0.1%)	22 (<0.1%)
Partially vaccinated	1,110	47 (4.2%)	8 (0.7%)	3 (0.3%)
No effective dose	2,765	251 (9.1%)	42 (1.5%)	7 (0.3%)
Under investigation	28,181	395 (1.4%)	40 (0.1%)	2 (<0.1%)
Not eligible for vaccination (aged 0-11 years)	12,328	93 (0.8%)	3 (<0.1%)	0 (0.0%)
Total	152,440	2,066 (1.4%)	197 (0.1%)	34 (<0.1%)

[513] ***COVID-19 vaccine surveillance report, Week 2***
UK Health Security Agency
January 13, 2022
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1047814/Vaccine-surveillance-report-week-2-2022.pdf

"**Executive Summary**: … Based on antibody testing of blood donors, **98.7%** of the adult population now have antibodies to COVID-19 from either infection or vaccination [*emphasis added]* …

Results: … In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated."

From Table 10 (below): COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission between week 50 2021 and week 1 2022:

- 13,514 Total (100%)
- 4,738 Not vaccinated (35.1%)
- **7,877** Second dose > or = 14 days before specimen date (**58.3%**)

Table 10. COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 50 2021 and week 1 2022

Please note that corresponding rates by vaccination status can be found in Table 12.

Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between week 50 2021 and week 1 2022	Total	Unlinked*	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]
	[These data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]					
Under 18	1,295	78	1,124	12	69	12
18 to 29	1,329	40	525	14	116	634
30 to 39	1,335	28	581	10	80	636
40 to 49	1,349	16	542	12	67	712
50 to 59	1,703	23	615	6	78	981
60 to 69	1,672	18	535	17	68	1,034
70 to 79	1,997	4	411	5	62	1,515
80 or over	2,834	3	405	7	66	2,353

* Individuals whose NHS numbers were unavailable to link to the NIMS.
[1] In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19.

From Table 11 (below): COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, between week 50 2021 and week 1 2022:

- 3,174 Total (100%)
- 924 Not vaccinated (29.1%)
- **2,089** Second dose > or = 14 days before specimen date (**65.8%**)

Table 11. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 50 2021 and week 1 2022
Please note that corresponding rates by vaccination status can be found in Table 12.
(a)

Death within 28 days of positive COVID-19 test by date of death between week 50 2021 and week 1 2022	Total**	Unlinked*	Not vaccinated	Received one dose (1 to 20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]
	[These data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]					
Under 18	8	0	8	0	0	0
18 to 29	23	0	15	0	0	8
30 to 39	64	0	37	0	3	24
40 to 49	115	2	69	0	5	39
50 to 59	263	2	116	1	15	129
60 to 69	499	10	181	0	21	287
70 to 79	715	6	196	2	35	476
80 or over	1,487	11	302	4	44	1,126

* Individuals whose NHS numbers were unavailable to link to the NIMS.
** number of deaths of people who had had a positive test result for COVID-19 and either died within 60 days of the first positive test or have COVID-19 mentioned on their death certificate.
[1] In the context of very high vaccine coverage in the population, even with a highly effective vaccine, it is expected that a large proportion of cases, hospitalisations and deaths would occur in vaccinated individuals, simply because a larger proportion of the population are vaccinated than unvaccinated and no vaccine is 100% effective. This is especially true because vaccination has been prioritised in individuals who are more susceptible or more at risk of severe disease. Individuals in risk groups may also be more at risk of hospitalisation or death due to non-COVID-19 causes, and thus may be hospitalised or die with COVID-19 rather than because of COVID-19.

[514] ***Public Health Scotland COVID-19 Statistical Report As at 10 January 2022***
Public Health Scotland
January 12, 2022
https://publichealthscotland.scot/media/11076/22-01-12-covid19-winter_publication_report.pdf
https://publichealthscotland.scot/media/9994/21-11-03-covid19-publication_report.pdf

Notes: Per Table 11 (below), from December 11th 2021 through January 7th 2022, Public Health Scotland identified 288,266 **COVID-19 cases**. Of this number:

42,565 (14.7%) were unvaccinated (885 cases per 100,000)

245,701 (85.3%) had received at least one dose

- One Dose – 1189 cases per 100,000
- Two Dose – 1938 cases per 100,000
- Three Dose – 1146 cases per 100,000

Table 11: Age-standardised case rate per 100,000 individuals by week and vaccination status, 11 December 2021 to 07 January 2022

	Unvaccinated		1 Dose	
Week	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	6,545	**482.87** (464.41 - 501.34)	2,952	**574.16** (538.46 - 609.85)
18 December - 24 December 2021	9,070	**721.39** (698.44 - 744.34)	4,639	**958.62** (911.03 - 1,006.20)
25 December - 31 December 2021	14,465	**1,242.10** (1,209.27 - 1,274.94)	7,657	**1,693.71** (1,631.31 - 1,756.11)
01 January 2022 – 07 January 2022	12,485	**1,092.80** (1,063.90 - 1,121.71)	6,702	**1,527.57** (1,462.52 - 1,592.63)
	2 Doses		Booster or 3rd Dose	
Week	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	20,788	**826.49** (809.83 - 843.16)	3,926	**458.39** (400.49 - 516.29)
18 December - 24 December 2021	35,123	**1,527.87** (1,501.86 - 1,553.88)	10,193	**902.02** (841.06 - 962.98)
25 December - 31 December 2021	54,860	**2,897.58** (2,859.92 - 2,935.23)	30,327	**1,755.69** (1,701.98 - 1,809.40)
01 January 2022 – 07 January 2022	35,119	**2,499.52** (2,462.50 - 2,536.53)	33,415	**1,466.76** (1,418.18 - 1,515.33)

Date are only based on PCR results. Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 6. The data displayed within the greyed-out section are considered preliminary and are subject to change as more data is updated. Age-standardised case rates are per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 6). On average, unvaccinated individuals are younger than individuals with two or more doses of COVID-19 vaccine. To compare across vaccination statuses (unvaccinated, 1 dose, 2 doses or booster/3 doses), age-standardised case rates are calculated to adjust for differences in age distribution. COVID-19 cases included in this table for the *age-standardised rates only includes individuals 10 years old and over. Although the majority of 10 and 11 year olds are currently not eligible for vaccination, the five-year age band standardised to the 2013 European Standard Population used in this analysis ranges from 10-14 years and therefore cases and denominators for these age groups are included.*

Per Table 12 (below), from December 11th 2021 through January 7th 2022, Public Health Scotland identified 2193 **COVID-19 hospitalizations**. Of this number:

545 (25%) were unvaccinated (63 hospitalizations per 100,000)

1648 (75%) had received at least one dose

- One Dose – 42 hospitalizations per 100,000
- Two Dose – 75 hospitalizations per 100,000
- Three Dose – 47 hospitalizations per 100,000

Table 12: Age-standardised rate of acute hospital admissions where an individual had a COVID-19 positive PCR test up to 14 days prior, on admission, or during their stay in hospital, by week and vaccination status, 11 December 2021 to 07 January 2022

	Unvaccinated		1 Dose	
Week	No. hospitalised	Age Standardised hospitalisation Rate per 100,000 with 95% confidence intervals	No. hospitalised	Age Standardised hospitalisation Rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	98	**43.94** (24.34 - 63.54)	20	**37.48** (8.44 - 66.53)
18 December - 24 December 2021	134	**64.55** (38.00 - 91.11)	14	**14.06** (-4.71 - 32.83)
25 December - 31 December 2021	168	**84.17** (56.69 - 111.65)	43	**53.62** (19.11 - 88.12)
01 January 2022 – 07 January 2022	145	**59.17** (26.42 - 91.92)	46	**63.78** (12.51 - 115.04)
	2 Doses		Booster or 3rd Dose	
Week	No. hospitalised	Age Standardised hospitalisation Rate per 100,000 with 95% confidence intervals	No. hospitalised	Age Standardised hospitalisation Rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	189	**46.46** (25.71 - 67.21)	75	**4.29** (3.07 - 5.50)
18 December - 24 December 2021	165	**45.21** (32.10 - 58.33)	116	**6.94** (5.36 - 8.53)
25 December - 31 December 2021	225	**78.91** (58.05 - 99.76)	273	**20.54** (15.80 - 25.28)
01 January 2022 – 07 January 2022	184	**130.14** (81.50 - 178.79)	298	**14.82** (12.12 - 17.53)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 6. The data displayed within the greyed-out section are considered preliminary and are subject to change as more data is updated. Age-standardised hospitalisation rates are per 100,000 people per week, standardised to the 2013 European Standard Population adjusted to only include individuals 16 years old and over (see Appendix 6).

Per Table 13 (below), from December 11th 2021 through January 7th 2022, Public Health Scotland identified 240 **COVID-19 related deaths**. Of this number:

46 (19%) were unvaccinated (4.8 deaths per 100,000)

194 (81%) had received at least one dose

- One Dose – 9.2 deaths per 100,000
- Two Dose – 7.7 deaths per 100,000
- Three Dose – .25 deaths per 100,000

Table 13: Number of confirmed COVID-19 related deaths by vaccination status at time of test and age-standardised mortality rate per 100,000, 04 December 2021 to 31 December 2021

	Unvaccinated		1 Dose	
Week	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
04 December - 10 December 2021	14	**5.56** (1.60 - 9.53)	6	**17.24** (3.36 - 31.12)
11 December - 17 December 2021	18	**7.13** (2.68 - 11.58)	3	**3.93** (0.00 - 9.22)
18 December - 24 December 2021	6	**1.72** (0.22 - 3.22)	7	**15.27** (2.87 - 27.66)
25 December - 31 December 2021	8	**4.79** (0.58 - 8.99)	1	**0.36** (0.00 - 1.05)
	2 Doses		Booster or 3rd Dose	
Week	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
04 December - 10 December 2021	56	**9.44** (6.78 - 12.10)	8	**0.26** (0.05 - 0.46)
11 December - 17 December 2021	36	**7.66** (5.03 - 10.28)	8	**0.20** (0.06 - 0.33)
18 December - 24 December 2021	24	**6.52** (3.78 - 9.25)	15	**0.33** (0.16 - 0.49)
25 December - 31 December 2021	21	**7.06** (3.82 - 10.30)	9	**0.21** (0.07 - 0.34)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 6. A confirmed COVID-19 related death is defined as an individual who has tested positive by PCR for SARS-CoV-2 at any time point and has COVID-19 listed as an underlying or contributory cause of death on the death certificate. Age-standardised mortality rates per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 6). This definition is for the purposes of evaluating the impact of the COVID-19 vaccine on confirmed COVID-19 deaths. The numbers reported in this section may differ from other published COVID-19 death data. Data are based on date of registration. In Scotland deaths must be registered within 8 days although in practice, the average time between death and registration is around 3 days. More information on days between occurrence and registration can be found on the NRS website.

[515] ***Over One-Third Of Vaccinated Americans Became Infected With COVID After The Jab: Poll***
Newsweek
Natalie Colarossi
January 11, 2022
https://www.newsweek.com/over-one-third-vaccinated-americans-became-infected-covid-after-jab-poll-1668027

> "In a new poll released by Axios/Ispos on Tuesday, 36 percent of respondents said they either recently tested positive or believe they had COVID after being fully vaccinated. That compares to just 22 percent of respondents in mid-December, and only six percent from last summer, according to the poll."

[516] ***COVID Deaths in U.S. Military Spike in Last Four Months Despite 96 Percent Being Vaccinated***
Newsweek
Alex J. Rouhandeh
January 10, 2022
https://www.newsweek.com/covid-deaths-us-military-spike-last-four-months-despite-96-percent-being-vaccinated-1667513

> "Over the 18 months between March 2020 to August 2021, America's armed forces experienced 43 deaths attributed to COVID-19. Over the past four months, from September through December, the military has seen the same number of deaths, according to a report from the Pentagon reviewed by Newsweek.

This increase in military deaths comes despite the fact that 96 percent of active-duty soldiers being fully vaccinated, a memo by the Pentagon states."

[517] ***Effectiveness of COVID-19 vaccines against Omicron or Delta infection***
Public Health Ontario and University of Toronto
Sarah A. Buchan, Hannah Chung, *et al*.
January 1, 2022
https://www.medrxiv.org/content/10.1101/2021.12.30.21268565v1.full-text

"**Results**: … receipt of 2 doses of COVID-19 vaccines was not protective against Omicron infection at any point in time, and VE [*vaccine effectiveness*] was **–38%** (95%CI, –61%, –18%) 120-179 days and **–42%** (95%CI, –69%, –19%) 180-239 days after the second dose. VE against Omicron was 37% (95%CI, 19-50%) ≥7 days after receiving an mRNA vaccine for the third dose.

Findings were consistent for any combination of 2 mRNA vaccines and 2 doses of BNT162b2 for the primary series."

[518] ***COVID-19 cases with Lineage B.1.1.529 (Omicron) or S-Gene Target Failure (SGTF) in Ontario: October 31, 2021 to December 29, 2021***
Public Health Ontario
December 31, 2021
https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-omicron-weekly-epi-summary.pdf?sc_lang=en

"**Highlights**: Across vaccination status, 14.4% of Omicron/SGTF cases were reported as unvaccinated and 77.3% were reported as breakthrough cases."

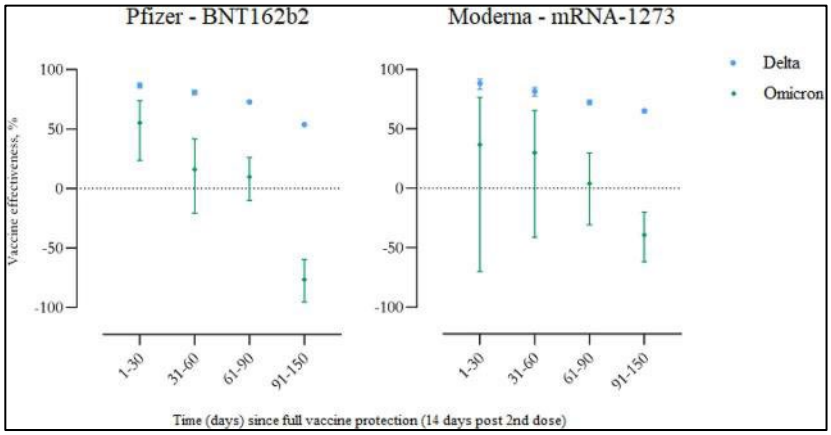
[519] ***Waning of SARS-CoV-2 booster viral-load reduction effectiveness***
Tel Aviv University and Maccabi Health Services (Israel)
Matan Levine-Tiefenbrun, Idan Yelin, *et al*.
December 29, 2021
https://www.medrxiv.org/content/10.1101/2021.12.27.21268424v1.full-text

"**Abstract**: The BNT162b2 COVID-19 vaccine has been shown to reduce viral load of breakthrough infections (BTIs), an important factor affecting infectiousness. This viral-load protective effect has been waning with time post the second vaccine and later restored with a booster shot. It is currently unclear though for how long this regained effectiveness lasts. Analyzing Ct values of SARS-CoV-2 qRT-DeclarPCR tests of over 22,000 infections during a Delta-variant-dominant period in Israel, we found that this viral-load reduction effectiveness **significantly declines within months** post the booster dose. Adjusting for age, sex and calendric date, Ct values of RdRp gene initially increased by 2.7 [CI: 2.3-3.0] relative to unvaccinated in the first month post the booster dose, yet then decayed to a difference of 1.3 [CI: 0.7-1.9] in the second month and **became small and insignificant in the third to fourth months**. The rate and magnitude of this post-booster decline in viral-load reduction effectiveness **mirror those observed post the second vaccine**. These results suggest **rapid waning of the booster's effectiveness in reducing infectiousness**, possibly affecting community-level spread of the virus [*emphasis added*]."

[520] ***Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1273 vaccination series: A Danish cohort study***
Statens Serum Institut (Denmark)
Christian Holm Hansen, Astrid Blicher Schelde, *et al*.
December 21, 2021
https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v1.full

"**Results**: By December 12, 2021, there were 5,767 identified Omicron cases in Denmark with a median age of 28 years (93% <60 years). Among those who had most recently completed primary vaccination, VE against Omicron was **55.2%** (95% confidence interval: 23.5 to 73.7%) and **36.7%** (−69.9 to 76.4%) for the BNT162b2 and mRNA-1273 vaccines, respectively, but with **evidence of rapid waning over the course of five months**.

Figure - Vaccine effectiveness against SARS-CoV-2 infection with the Delta and Omicron variants, shown separately for the BNT162b2 and mRNA-1273 vaccines. Vertical bars indicate 95% confidence intervals."



[521] ***SARS-CoV-2 B.1.1.529 (Omicron) Variant — United States, December 1–8, 2021***
Centers for Disease Control and Prevention (CDC)
December 17, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7050e1-H.pdf

"**Characteristics of the First Investigated U.S. COVID-19 Cases Attributed to the Omicron Variant**

Details are available for 43 cases of COVID-19 attributed to the Omicron variant…

Among these cases of COVID-19 attributed to the Omicron variant, **34 (79%) occurred in persons who completed the primary series** of an FDA-authorized or approved COVID-19 vaccine ≥14 days before symptom onset or receipt of a positive SARS-CoV-2 test result, **including 14 who had received an additional or booster dose** [*emphasis added*]."

[522] ***Covid-19 Rapport om omikronvarianten***
Statens Serum Institut (Denmark)
December 17, 2021
https://www.ssi.dk/-/media/cdn/files/covid19/omikron/statusrapport/rapport-omikronvarianten-17122021-ep96.pdf

Table 4. Vaccination status for individuals ≥12 years infected with Omicron compared to other variants, data included in the table are from 22 November to 14 December 2021

Tabel 4. Vaccinationsstatus for personer ≥12 år med omikron-infektion sammenlignet med andre varianter i perioden fra og med 22. november 2021 til og med 14. december 2021

Vaccination status (12+ year olds)	Other variants (No. of cases)	Other variants (%)	Omicron (No. of cases)	Omicron (%)
Booster vaccinated	6,679	7.3	1,074	10.3
Fully vaccinated	60,174	66.0	8,235	78.7
Not vaccinated	21,364	23.5	947	9.0
Received first dose	2,887	3.2	214	2.0
Total	91,104	100.0	10,470	100.0

[523] ***Highly Vaccinated South Korea Can't Slow Down Covid-19***
Wall Street Journal
Dasl Yoon
December 16, 2021
https://www.wsj.com/articles/highly-vaccinated-south-korea-cant-slow-down-covid-19-11639652626

> "Some **81.5%** of South Korea's 52 million residents are **fully vaccinated**, according to Our World in Data, trailing only Portugal, Chile and Iceland among members of the Organization for Economic Cooperation and Development…
>
> South Korea has reported 148 Omicron variant cases, though Delta remains the dominant force in what has been the country's worst outbreak of the pandemic. Daily cases regularly exceed 7,000, tripling in the past month. **South Korea has never seen so many critically ill patients**, with 90% of ICU beds for Covid-19 patients occupied in the Seoul metropolitan area. **Deaths are at record levels**, doubling from last month [*emphasis added*]."

[524] ***Omicron wave driven by 'young, healthy, vaccinated' population***
The Telegraph
Sarah Newey and Will Brown
December 13, 2021
https://www.telegraph.co.uk/global-health/science-and-disease/omicron-wave-driven-young-healthy-vaccinated-population/

> "The omicron epidemic is being driven by young, vaccinated people, according to mounting data from countries as diverse as the UK, Denmark and South Africa…
>
> Data from Denmark – a world leader in genetic sequencing – shows that, of 3,437 omicron cases detected, just over 70 per cent have been among those younger than 40, according to the breakdown from the Statens Serum Institut published on Monday.

Some **75 per cent** of these cases **were in fully vaccinated individuals** [*emphasis added*], the institute added, comfirming that even the double jabbed can carry the virus."

[525] ***Most reported U.S. Omicron cases have hit the fully vaccinated – CDC***
Reuters
Mrinalika Roy
December 10, 2021
https://www.reuters.com/world/us/most-reported-us-omicron-cases-have-hit-fully-vaccinated-cdc-2021-12-10/

"The U.S. Centers for Disease Control and Prevention (CDC) said that of the 43 cases attributed to Omicron variant, 34 people had been fully vaccinated. Fourteen of them had also received a booster."

[526] ***552 Fully Vaccinated Oregon Residents Died Of COVID-19, Half Received Pfizer Vaccine***
International Business Times
Danielle Ong
December 6, 2021
https://www.ibtimes.com/552-fully-vaccinated-oregon-residents-died-covid-19-half-received-pfizer-vaccine-3352533

"Since the beginning of the pandemic, **health authorities in Oregon have recorded a total of 552 breakthrough COVID-19 deaths** throughout the state [*emphasis added*] Of the total number of deaths, 273 people had been fully vaccinated with the Pfizer COVID-19 vaccine. At least 144 received the Moderna vaccine and 78 were given the Johnson & Johnson shots, according to data from the Oregon Health Authority.

The recent report also showed that there were 4,134 new COVID-19 cases recorded between Nov. 21 and Nov. 27. At least 1,186 were breakthrough infections.

As of Dec. 2, Oregon reported a total of 45,545 coronavirus infections among the fully vaccinated."

[527] ***COVID-19: 75 more Omicron cases found in England - as UKHSA releases risk assessment***
Sky News
Thomas Moore and Andy Hayes
December 4, 2021
https://news.sky.com/story/covid-19-over-half-of-uk-omicron-cases-happened-after-two-jabs-as-ukhsa-releases-risk-assessment-12485607

"Earlier, it emerged that more than half of those confirmed to have been infected with Omicron in the UK were double jabbed - based on figures released before this evening's update.

A technical briefing from the UKHSA said 12 of the 22 known cases up to 30 November had been fully vaccinated.

Another two people infected had been given their first dose at least four weeks earlier."

[528] ***Dutch say 14 air passengers from S. Africa with Omicron were vaccinated***
Reuters
Toby Sterling
December 2, 2021
https://www.reuters.com/world/europe/dutch-covid-19-quarantine-ends-most-safrica-passengers-authorities-2021-12-02/

> "Dutch health authorities on Thursday said most of the 62 people who tested positive for COVID-19 after arriving on two flights from South Africa last week had been vaccinated, lending weight to a call for pre-flight testing regardless of vaccination status.
>
> In addition, all 14 passengers who were later found to have been infected with the Omicron variant were vaccinated, health officials said on Thursday."

[529] ***COVID-19 vaccine surveillance report, Week 48***
UK Health Security Agency
December 2, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1037987/Vaccine-surveillance-report-week-48.pdf

> "**Executive Summary**: … Based on antibody testing of blood donors, **98.1%** of the adult population now have antibodies to COVID-19 from either infection or vaccination compared to **18.7% that have antibodies from infection alone** [*emphasis added]* …
>
> **Results**: … In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated."
>
> **From Table 10 (below)**: COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate:
>
> - 3,571 Total (100%)
> - 695 Not vaccinated (19.5%)
> - **2,750** Second dose > or = 14 days before specimen date (**77.0%**)

COVID-19 vaccine surveillance report – week 48

Table 10. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 44 and week 47 2021
Please note that corresponding rates by vaccination status can be found in Table 11.
(a)

Death within 28 days of positive COVID-19 test by date of death between week 44 and week 47 2021	Total**	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[†]
	[These data should be interpreted with caution. See information below in footnote about the correct interpretation of these figures]					
Under 18	8	1	7	0	0	0
18-29	13	0	8	0	3	2
30-39	35	2	24	0	3	6
40-49	100	3	50	0	3	44
50-59	264	5	107	0	12	140
60-69	531	4	146	0	19	362
70-79	1002	6	164	1	13	818
≥80	1,618	9	189	5	37	1,378

[530] ***Vaccination Status of COVID-19 Deaths in Ireland between 1st April 2021 and 30th October 2021***
Health Protection Surveillance Center (Ireland)
November 2021
https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/surveillance/vaccinationstatusweeklyreports/Death%20and%20Vaccination%20Report.pdf

"Between April 1st and October 30th 2021

- 535 persons with a laboratory confirmed COVID-19 infection, were notified to the Health Protection Surveillance Centre (HPSC) as having died due to COVID-19.
- **313/535 (58.5%) deaths were notified in persons who had received at least one dose** of COVID-19 vaccine prior to death [*emphasis added*].
- 253/535 (47.3%) of the notified deaths had an epidemiological date 14 days or more after receiving both doses of a 2-dose regimen or 1 dose of a 1-dose regimen and are considered as vaccine breakthrough infections – see technical note."

[531] ***Elapsed time since BNT162b2 vaccine and risk of SARS-CoV-2 infection: test negative design study***
British Medical Journal (Leumit Health Services, Israel)
Ariel Israel, Eugene Merzon, *et al*.
November 25, 2021
https://www.bmj.com/content/375/bmj-2021-067873

"**Results**: 83,057 adults received an RT-PCR test for SARS-CoV-2 during the study period and 9.6% had a positive result. Time elapsed since the vaccine injection was significantly longer in individuals who tested positive (P<0.001). Adjusted odds ratio for infection at time intervals >90 days since vaccination were significantly increased compared with the reference of <90 days: 2.37 (95% confidence interval 1.67 to 3.36) for 90-119 days, 2.66 (1.94 to 3.66) for 120-149 days, 2.82 (2.07 to 3.84) for 150-179 days, and 2.82 (2.07 to 3.85) for ≥180 days (P<0.001 for each 30 day interval).

Conclusions: In this large population of adults tested for SARS-CoV-2 by RT-PCR after two doses of mRNA BNT162b2 vaccine, a gradual increase in the risk of infection was seen for individuals who received their second vaccine dose after at least 90 days."

[532] ***COVID Cases Are Surging in the Five Most Vaccinated States***
Newsweek
Jack Dutton
November 25, 2021
https://www.newsweek.com/covid-cases-are-surging-five-most-vaccinated-states-1653298

"The five most vaccinated states in the United States—Vermont, Rhode Island, Maine, Connecticut and Massachusetts—are all experiencing surges in new COVID-19 cases, as the Biden administration urges people over 50 to get their booster jabs.

Vermont, which is the most vaccinated state, with 73 percent of its population fully jabbed, saw an 18 percent rise in new daily COVID cases over the last 14 days before November 24, according to New York Times data…

Rhode Island, which is 72 percent vaccinated, saw a 69 percent rise in new cases during that same 14-day time period. The state recorded an average of 480 new cases a day between November 17-24.

Maine, also 72 percent vaccinated, saw a 35 percent rise (now 694 daily average of new cases), while Connecticut, which is 72 percent vaccinated, saw a 120 percent spike in daily COVID cases (now 751 daily average of new cases).

Massachusetts, which is 71 percent vaccinated, saw a rise of 81 percent during the last 14 days before November 24. On average, it has recorded 2,881 cases a day between November 17-24."

[533] ***Increased risk of infection with SARS-CoV-2 Beta, Gamma, and Delta variant compared to Alpha variant in vaccinated individuals***
National Institute for Public Health and the Environment (Netherlands)
Stijn P. Andeweg, Harry Vennema, *et al*.
November 24, 2021
https://www.medrxiv.org/content/10.1101/2021.11.24.21266735v1

"**Abstract**: The extent to which severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern (VOC) break through infection- or vaccine-induced immunity is not well understood. Here, we analyze 28,578 sequenced SARS-CoV-2 samples from individuals with known immune status obtained through national community testing in the Netherlands from March to August 2021. We find evidence for an **increased risk of infection** by the Beta (B.1.351), Gamma (P.1), or Delta (B.1.617.2) variants compared to the Alpha (B.1.1.7) variant **after vaccination**. No clear differences were found between vaccines. However, the effect was larger in the first 14-59 days after complete vaccination compared to 60 days and longer. In contrast to vaccine-induced immunity, **no increased risk for reinfection** with Beta, Gamma or Delta variants relative to Alpha variant was found **in individuals with infection-induced immunity** [*emphasis added*]."

[534] **Correspondence:** ***COVID-19: stigmatising the unvaccinated is not justified***
The Lancet
Dr. Günter Kampf, Institute for Hygiene and Environmental Medicine
November 20, 2021
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02243-1/fulltext

"There is increasing evidence that vaccinated individuals continue to have a relevant role in transmission. In Massachusetts, USA, a total of 469 new COVID-19 cases were detected during various events in July, 2021, and 346 (74%) of these cases were in people who were fully or partly vaccinated, 274 (79%) of whom were symptomatic. Cycle threshold values were similarly low between people who were fully vaccinated (median 22.8) and people who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median 21.5), indicating a high viral load even among people who were fully vaccinated.

In the USA, a total of 10,262 COVID-19 cases were reported in vaccinated people by April 30, 2021, of whom 2725 (26.6%) were asymptomatic, 995 (9.7%) were hospitalised, and 160 (1.6%) died. In Germany, 55.4% of symptomatic COVID-19 cases in patients aged 60 years or older were in fully vaccinated individuals, and this proportion is increasing each week. In Münster, Germany, new cases of COVID-19 occurred in at least 85 (22%) of 380 people who were fully vaccinated or who had recovered from COVID-19 and who attended a nightclub.

People who are vaccinated have a lower risk of severe disease but are still a relevant part of the pandemic. It is therefore wrong and dangerous to speak of a pandemic of the unvaccinated. Historically, both the USA and Germany have engendered negative experiences by stigmatising parts of the population for their skin colour or religion. I call on high-level officials and scientists to stop the inappropriate stigmatisation of unvaccinated people, who include our patients, colleagues, and other fellow citizens, and to put extra effort into bringing society together."

[535] ***Transmission potential of vaccinated and unvaccinated persons infected with the SARS-CoV-2 Delta variant in a federal prison, July—August 2021***
CDC COVID Response Team
Phillip P. Salvatore, Christine C. Lee, *et al*.
November 19, 2021
https://www.medrxiv.org/content/10.1101/2021.11.12.21265796v1.full-text

"**Background**: The extent to which vaccinated persons who become infected with SARS-CoV-2 contribute to transmission is unclear. During a SARS-CoV-2 Delta variant outbreak among incarcerated persons with high vaccination rates in a federal prison, we assessed markers of viral shedding in vaccinated and unvaccinated persons…

Results: A total of 978 specimens were provided by 95 participants, of whom 78 (82%) were fully vaccinated and 17 (18%) were not fully vaccinated. **No significant differences were detected** in duration of RT-PCR positivity among fully vaccinated participants (median: 13 days) versus those not fully vaccinated (median: 13 days; p=0.50), or in duration of culture positivity [*emphasis added*] (medians: 5 days and 5 days; p=0.29).

Conclusions: As this field continues to develop, clinicians and public health practitioners should consider vaccinated persons who become infected with SARS-CoV-2 to be no less infectious than unvaccinated persons. These findings are critically important, especially in congregate settings where viral transmission can lead to large outbreaks."

[536] **Letter: *The epidemiological relevance of the COVID-19-vaccinated population is increasing***
The Lancet
Günter Kampf (Institute for Hygiene and Environmental Medicine, Germany)
November 19, 2021
https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(21)00258-1/fulltext

"High COVID-19 vaccination rates were expected to reduce transmission of SARS-CoV-2 in populations by reducing the number of possible sources for transmission and thereby to reduce the burden of COVID-19 disease. Recent data, however, indicate that the epidemiological relevance of COVID-19 vaccinated individuals is increasing. In the UK it was described that secondary attack rates among household contacts exposed to fully vaccinated

index cases was similar to household contacts exposed to unvaccinated index cases (25% for vaccinated vs 23% for unvaccinated). 12 of 31 infections in fully vaccinated household contacts (39%) arose from fully vaccinated epidemiologically linked index cases. Peak viral load did not differ by vaccination status or variant type. In Germany, the rate of symptomatic COVID-19 cases among the fully vaccinated ("breakthrough infections") is reported weekly since 21 July 2021 and was 16.9% at that time among patients of 60 years and older. **This proportion is increasing week by week** and was **58.9% on 27 October 2021** (Figure 1) providing clear evidence of the increasing relevance of the fully vaccinated as a possible source of transmission [*emphasis added*]. A similar situation was described for the UK. Between week 39 and 42, a total of 100,160 COVID-19 cases were reported among citizens of 60 years or older. 89,821 occurred among the fully vaccinated (89.7%), 3.395 among the unvaccinated (3.4%). One week before, the COVID-19 case rate per 100.000 was higher among the subgroup of the vaccinated compared to the subgroup of the unvaccinated in all age groups of 30 years or more. In Israel a nosocomial outbreak was reported involving 16 healthcare workers, 23 exposed patients and two family members. The source was a fully vaccinated COVID-19 patient. The vaccination rate was 96.2% among all exposed individuals (151 healthcare workers and 97 patients). Fourteen fully vaccinated patients became severely ill or died, the two unvaccinated patients developed mild disease. The US Centres for Disease Control and Prevention (CDC) identifies four of the top five counties with the highest percentage of fully vaccinated population (99.9–84.3%) as "high" transmission counties. Many decisionmakers assume that the vaccinated can be excluded as a source of transmission. It appears to be **grossly negligent** to ignore the vaccinated population as a possible and relevant source of transmission when deciding about public health control measures [*emphasis added*]."

[537] ***Gibraltar cancels Christmas celebrations amid Covid spike***
Express (UK)
Millie Cooke
November 17, 2021
https://www.express.co.uk/news/uk/1521786/Gibraltar-news-covid-cases-rise-Christmas-lockdown

"Gibraltar has seen a steady increase in active cases of COVID-19 throughout October and November, which has gained pace over the past few days.

Health Minister, the Hon Samantha Sacramento, described the increase in case numbers as 'drastic'…

Gibraltar has seen an average of 47 cases per day over the last seven days. The country saw 124 new cases appear over the weekend, taking the number of active cases to 474.

Gilbraltar currently mandates mask-wearing in all shops, medical establishments, airports, enclosed places of worship and on public transport.

Close contacts of an active case are also required to wear a mask when out in public, in the workplace, shopping or using public transport.

In March, Gibraltar became **the first nation in the world to fully vaccinate its entire adult population** against coronavirus [*emphasis added*]."

[538] ***Vermont leads nation in new COVID cases and vaccination rate***
News 10 (ABC News)
Brian Wallstin
November 16, 2021
https://www.news10.com/news/coronavirus/vermont-leads-nation-in-new-covid-cases-and-vaccination-rate/

> "Vermont and Rhode Island report 72% of residents 12 and older have been fully vaccinated by Johnson & Johnson's single-dose vaccine or the two-dose series made by Pfizer-BioNTech and Moderna, according to the The New York Times vaccine tracker. Factor in children 5 and older, and Vermont's fully vaccinated rate rises to 74%, or more than 438,000 people, according to the most recent data from the Department of Health.
>
> Meanwhile, new cases in the last 14 days in Vermont are up 82%, according to the Times."

[539] ***Surveillance of vaccine status in confirmed COVID-19 episodes and hospital inpatients***
Public Health Wales
November 14, 2021
https://www2.nphs.wales.nhs.uk/CommunitySurveillanceDocs.nsf/61c1e930f9121fd080256f2a004937ed/a4f536f72da3962b8025875a0031b3c8/$FILE/Survey%20of%20vaccine%20status%20in%20cases%20and%20hospital%20inpatients.pdf

Table 1: Comparison of confirmed episodes of COVID-19 from 01/11/2021 up to and including 14/11/2021 between fully vaccinated population and not fully vaccinated population in Wales. Vaccination status is as per the beginning of this period (01/11/2021).

Age	Fully vaccinated population in Wales as of 01/11/2021			Unvaccinated population in Wales as of 01/11/2021		
	Denominator	No of confirmed episodes	Rate per 100,000 population	Denominator	No of confirmed episodes	Rate per 100,000 population
Under 18	2,824	14	496	144,427	2,563	1,775
Aged 18-60	1,426,451	13,729	962	308,477	2,373	769
Over 60	839,049	4,327	516	47,686	126	264
Total	**2,268,324**	**18,070**	**797**	**500,590**	**5,062**	**1,011**

NB: *A "fully vaccinated" individual is a person who was vaccinated with a full dose course and has had at least 14 days elapsed since their dose 2 day, as of the start of the 2 week period*

Table 4: Vaccine status in COVID-19 hospital inpatients as of 09/11/2021

Vaccine status at specimen collection	All Patients		Under 18		Aged 18- 60		Over 60	
	n	%	n	%	n	%	n	%
Unvaccinated	96	12.8%	8	36.4%	52	34.9%	36	6.2%
Vaccinated- first dose only	7	0.9%	0	0.0%	3	2.0%	4	0.7%
Vaccinated- Both doses	625	83.6%	0	0.0%	92	61.7%	533	92.4%
Unknown	20	2.7%	14	63.6%	2	1.3%	4	0.7%
Total	**748**	**100%**	**22**	**100%**	**149**	**100%**	**577**	**100%**

NB: All of the 625 patients who were fully vaccinated before testing positive for COVID-19 all had their second vaccine dose 14 days or more before their specimen collection date. The median age of inpatient COVID 19 hospital inpatients, is 74 years (range 0-104)

[540] ***Shedding of Infectious SARS-CoV-2 Despite Vaccination***
University of Wisconsin-Madison
Kasen K. Riemersma, Brittany E. Grogan, *et al*.
November 6, 2021
https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v6.full-text

"**Abstract**: The SARS-CoV-2 Delta variant is highly transmissible and contains mutations that confer partial immune escape. We compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) or unvaccinated (n=389) individuals. We observed low Ct values (<25) in 212 of 310 fully vaccinated (**68%**) and 246 of 389 (**63%**) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people. To determine whether infectious virus titers differed in vaccinated and unvaccinated persons, we performed plaque assays on an additional set of 48 samples with Ct <25, **finding no difference in infectious virus titer between groups** [*emphasis added*]."

[541] ***COVID-19: Ireland's Co Waterford has one of the highest vaccination rates in the world - so why are cases surging?***
Sky News
Stephen Murphy
November 6, 2021
https://news.sky.com/story/covid-19-irelands-co-waterford-has-one-of-the-highest-vaccination-rates-in-the-world-so-why-are-cases-surging-12461642

"Waterford, in south-eastern Ireland, epitomises the country's coronavirus conundrum. Why is there a surge in COVID-19 cases in a nation where around 92% of all adults are fully vaccinated?

A massive 99.5% of adults over the age of 18 in Co Waterford are double-jabbed. That's thought to be one of the highest rates of any region anywhere in the world.

But, according to the Health Protection Surveillance Centre, the county now tops the national infection league table, with a 14-day incidence rate of 1,294 per 100,000."

[542] ***COVID-19 vaccine surveillance report, Week 44***
UK Health Security Agency
November 4, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1032671/Vaccine_surveillance_report_-_week_44.pdf

"**Executive Summary**: … Based on antibody testing of blood donors, **98.0%** of the adult population now have antibodies to COVID-19 [*emphasis added]* from either infection or vaccination compared to 18.7% that have antibodies from infection alone…

Results: … In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated."

Table 2. COVID-19 cases by vaccination status between week 40 and week 43 2021
Please note that corresponding rates by vaccination status can be found in Table 5.

Cases reported by specimen date between week 40 and week 43 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date
Under 18	397484	23778	336893	20041	15954	818
18-29	75211	7955	24097	701	8809	33649
30-39	113717	8476	25832	665	7252	71492
40-49	159478	8580	15717	291	4204	130686
50-59	114282	5853	6701	81	1925	99722
60-69	63474	3353	2484	23	835	56779
70-79	37535	2037	917	16	260	34305
≥80	14043	1002	471	7	224	12339

Table 3. COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 40 and week 43 2021
Please note that corresponding rates by vaccination status can be found in Table 5.

Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between week 40 and week 43 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date
Under 18	581	20	539	12	9	1
18-29	323	7	212	3	30	71
30-39	665	9	425	5	37	189
40-49	1006	16	472	5	45	468
50-59	1233	18	474	1	51	689
60-69	1308	7	318	2	29	952
70-79	1802	5	198	3	32	1564
≥80	1804	3	168	0	33	1600

Table 4. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 40 and week 43 2021

Please note that corresponding rates by vaccination status can be found in Table 5.

(a)

Death within 28 days of positive COVID-19 test by date of death between week 40 and week 43 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date
Under 18	6	0	6	0	0	0
18-29	9	0	7	0	0	2
30-39	25	1	17	0	2	5
40-49	73	1	37	0	1	34
50-59	179	4	81	0	5	89
60-69	420	3	118	0	14	285
70-79	809	2	115	0	18	674
≥80	1564	4	157	0	45	1358

[543] ***SARS-CoV-2 vaccine protection and deaths among US veterans during 2021***
Science (George Mason University)
Barbara A. Cohn, Piera M. Cirillo, Caitlin C. Murphy, Nickilou Y. Krigbaum, and Arthur W. Wallace
November 4, 2021
https://www.science.org/doi/10.1126/science.abm0620

"**Abstract**: We report SARS-CoV-2 vaccine effectiveness against infection (VE-I) and death (VE-D) by vaccine type (n = 780,225) in the Veterans Health Administration, covering 2.7% of the U.S. population. From February to October 2021, **VE-I declined from 87.9% to 48.1%**, and the decline was greatest for the Janssen vaccine resulting in a VE-I of 13.1% [*emphasis added*]."

[544] ***Public Health Scotland COVID-19 Statistical Report As at 01 November 2021***
Public Health Scotland
November 3, 2021
https://publichealthscotland.scot/media/9994/21-11-03-covid19-publication_report.pdf

Page 43: In Scotland for the period 10/2/2021 through 10/29/2021, Table 19 indicates a total of **552** "acute hospital admissions" with COVID-19 amongst the unvaccinated and **1,731** such admissions amongst recipients of two vaccination doses.

Table 19: Age-standardised rate of acute hospital admissions where an individual had a COVID-19 positive PCR test up to 14 days prior, on admission, or during their stay in hospital, by week and vaccination status, 02 October 2021 to 29 October 2021

	Unvaccinated		1 Dose		2 Doses	
Week/Vaccination Status	No. hospitalised	Age Standardised Hospitalisation Rate per 100,000 with 95% confidence intervals	No. hospitalised	Age Standardised Hospitalisation Rate per 100,000 with 95% confidence intervals	No. hospitalised	Age Standardised Hospitalisation Rate per 100,000 with 95% confidence intervals
02 October - 08 October 2021	161	**19.07** (14.81 - 23.34)	21	**19.22** (7.62 - 30.83)	441	**8.71** (7.87 - 9.54)
09 October - 15 October 2021	118	**15.49** (11.44 - 19.54)	16	**11.01** (3.85 - 18.18)	402	**7.89** (7.10 - 8.67)
16 October - 22 October 2021	131	**19.69** (15.10 - 24.27)	22	**13.90** (4.46 - 23.34)	449	**8.76** (7.94 - 9.58)
23 October - 29 October 2021	142	**20.12** (15.56 - 24.67)	16	**10.46** (1.67 - 19.25)	439	**8.44** (7.65 - 9.24)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 9. The data displayed within the greyed-out section (1 week) are considered preliminary and are subject to change as more data is updated. Age-standardised hospitalisation rates are per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 9).

Page 47: In Scotland for the period 9/25/2021 through 10/22/2021, Table 20 indicates a total of **64** "COVID-19 related deaths" amongst the unvaccinated and **454** such deaths amongst recipients of two vaccination doses.

Table 20: Number of confirmed COVID-19 related deaths by vaccination status at time of test and age-standardised mortality rate per 100,000, 25 September 2021 to 22 October 2021

	Unvaccinated		1 Dose		2 Doses	
Week/Vaccination Status	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
25 September - 01 October 2021	22	**6.59** (3.54 - 9.63)	4	**9.04** (0.05 - 18.03)	114	**2.23** (1.82 - 2.64)
02 October - 08 October 2021	19	**5.05** (2.48 - 7.61)	0	**0.00** (0.00 - 0.00)	106	**2.10** (1.70 - 2.51)
09 October - 15 October 2021	15	**5.03** (2.27 - 7.79)	4	**9.22** (-0.05 - 18.48)	120	**2.35** (1.93 - 2.77)
16 October - 22 October 2021	8	**1.90** (0.44 - 3.36)	4	**10.58** (0.17 - 21.00)	114	**2.20** (1.79 - 2.60)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 9. A confirmed COVID-19 related death is defined as an individual who has tested positive by PCR for SARS-CoV-2 at any time point and has COVID-19 listed as an underlying or contributory cause of death on the death certificate. Age-standardised mortality rates per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 9). This definition is for the purposes of evaluating the impact of the COVID-19 vaccine on confirmed COVID-19 deaths. The numbers reported in this section may differ from other published COVID-19 death data. Data are based on date of registration. In Scotland deaths must be registered within 8 days although in practice, the average time between death and registration is around 3 days. More information on days between occurrence and registration can be found on the NRS website.

[545] ***Viral loads of Delta-variant SARS-CoV-2 breakthrough infections after vaccination and booster with BNT162b2***
Nature Medicine
Matan Levine-Tiefenbrun, Idan Yelin, *et al*.
November 2, 2021
https://www.nature.com/articles/s41591-021-01575-4

> "**Abstract**: … By analyzing viral loads of over 16,000 infections during the current, Delta-variant-dominated pandemic wave in Israel, we found that BTIs [*breakthrough infections*] in recently fully vaccinated individuals have lower viral loads than infections in unvaccinated individuals. However, this effect starts to decline 2 months after vaccination and **ultimately vanishes 6 months or longer after vaccination** [*emphasis added*]."

[546] ***Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study***
Infectious Diseases (The Lancet)
Anika Singanayagam, Seran Hakki, *et al*.
October 29, 2021
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext

> "**Background**: The SARS-CoV-2 delta (B.1.617.2) variant is highly transmissible and spreading globally, including in populations with high vaccination rates. We aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community…
>
> **Interpretation**: … [F]ully vaccinated individuals with breakthrough infections have **peak viral load similar to unvaccinated cases** and **can efficiently transmit infection** in household settings, including to fully vaccinated contacts."

[547] ***COVID-19 vaccine surveillance report, Week 43***
UK Health Security Agency
October 28, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1029606/Vaccine-surveillance-report-week-43.pdf

"**Results**: … In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated…"

Table 2. COVID-19 cases by vaccination status between week 39 and week 42 2021

Cases reported by specimen date between week 39 and week 42 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]
Under 18	411,079	24,798	355,008	16,640	13,812	821
18-29	68,780	7,713	22,436	686	8,532	29,413
30-39	102,344	7,858	23,748	645	6,856	63,237
40-49	145,641	7,989	14,336	291	3,962	119,063
50-59	102,009	5,330	6,091	81	1,767	88,740
60-69	54,020	2,968	2,167	22	702	48,161
70-79	32,909	1,822	794	14	254	30,025
≥80	13,231	936	434	7	219	11,635

Table 3. COVID-19 cases presenting to emergency care (within 28 days of a positive specimen) resulting in an overnight inpatient admission by vaccination status between week 39 and week 42 2021

Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between week 39 and week 42 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]
Under 18	633	17	592	12	11	1
18-29	324	8	212	2	28	74
30-39	708	10	446	2	47	203
40-49	991	14	495	5	40	437
50-59	1,139	13	447	1	46	632
60-69	1,177	12	288	3	33	841
70-79	1,642	1	195	3	34	1,409
≥80	1,724	2	157	0	38	1,527

Table 4. COVID-19 deaths (a) within 28 days and (b) within 60 days of positive specimen or with COVID-19 reported on death certificate, by vaccination status between week 39 and week 42 2021

(a)

Death within 28 days of positive COVID-19 test by date of death between week 39 and week 42 2021	Total**	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date[1]
Under 18	5	0	4	1	0	0
18-29	11	1	7	0	0	3
30-39	25	0	18	0	1	6
40-49	65	1	35	0	1	28
50-59	159	3	74	0	5	77
60-69	374	3	105	0	16	250
70-79	736	2	101	0	21	612
≥80	1,397	5	143	0	40	1,209

[548] ***Waning Immunity after the BNT162b2 Vaccine in Israel***
The New England Journal of Medicine (NEJM)
Yair Goldberg, Micha Mandel, *et al*.
October 27, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2114228

"**Conclusions**: These findings indicate that immunity against the delta variant of SARS-CoV-2 waned in all age groups a few months after receipt of the second dose of vaccine…

Discussion: … [A]pproximately **two thirds of the cases of severe Covid-19** in Israel during the study period [*July 11 to 31, 2021*] **occurred in persons who had received two doses of the BNT162b2 vaccine** [*Pfizer-BioNTech - emphasis added*]."

[549] ***SARS-CoV-2 Vaccine Breakthrough Surveillance and Case Information Resource***
Washington State Department of Health
October 27, 2021
https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/data-tables/420-339-VaccineBreakthroughReport.pdf

"Vaccine breakthrough occurs when someone gets infected with an organism they are fully vaccinated against. For the COVID-19 vaccine, this means someone tests positive for SARS-CoV-2 two weeks or more after receiving the full series of an authorized COVID-19 vaccine…

At a Glance (data from January 17, 2021 - October 16, 2021) - 59,543 SARS-CoV-2 vaccine breakthrough cases have been identified in Washington State."

[550] ***Effectiveness of Covid-19 Vaccination Against Risk of Symptomatic Infection, Hospitalization, and Death Up to 9 Months: A Swedish Total-Population Cohort Study***
The Lancet (University of Umea)
Peter Nordstrom, Marcel Ballin, and Anna Nordstrom
October 25, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3949410

"**Methods**: A retrospective cohort study was conducted using Swedish nationwide registries. The cohort comprised 842,974 pairs (N=1,684,958), including individuals vaccinated with 2 doses of ChAdOx1 nCoV-19, mRNA-1273 [*Moderna*], or BNT162b2 [*Pfizer*], and matched unvaccinated individuals. Cases of symptomatic infection and severe Covid-19 (hospitalization or 30-day mortality after confirmed infection) were collected from 12 January to 4 October 2021.

Findings: **Vaccine effectiveness of BNT162b2 against infection waned progressively** from 92% at day 15-30 **to 47% at day 121-18**0, and from day 211 and onwards **no effectiveness could be detected**… The effectiveness waned slightly slower for mRNA-1273, being estimated to 59% (95% CI, 18-79) from day 181 and onwards. In contrast, effectiveness of ChAdOx1 nCoV-19 was generally lower and waned faster, with no effectiveness detected from day 121 and onwards… Overall, vaccine effectiveness was lower and waned faster among men and older individuals. For the outcome severe Covid-19, effectiveness waned from 89% at day 15-30 to **42% from day 181 and onwards**, with sensitivity analyses showing notable waning among men, **older frail individuals**, and **individuals with comorbidities**."

[551] **Press-conference video (2m): Remarks by Florida Attorney General, Dr. Joseph A. Ladapo**
October 25, 2021
https://www.bitchute.com/video/DKPJqkwZdezW/

Ladapo: “As we now know, these vaccines are not preventing transmission. Sure, they reduce the likelihood of transmission -- and even that is sort of questionable depending on how far out you go -- but they're not preventing it. I've heard some leaders say things like, 'We'll create safe workplaces by mandating these vaccines.' Well, they're really decoupled. Because the infections can still happen whether people are vaccinated or not. I mean, that's very obvious.

And you remember, these people were also telling you that all these breakthrough infections were rare. Well, they're obviously not rare. In fact, they're common, and so that’s the truth.

So this idea… that the vaccine mandates are needed to create safe workplaces is a complete lie, it's continued to be repeated, and you should know that it's not at all backed up by science. In fact, the science says something that's completely the opposite. And that’s a fact.

Part of the reason that some people are not comfortable with these vaccines is because of the climate of scientific dishonesty about the science -- whether it's natural immunity, denial of that in the face of data… or in the case of the vaccines, open, honest discussions about both effectiveness and safety… There's been dishonesty around that…

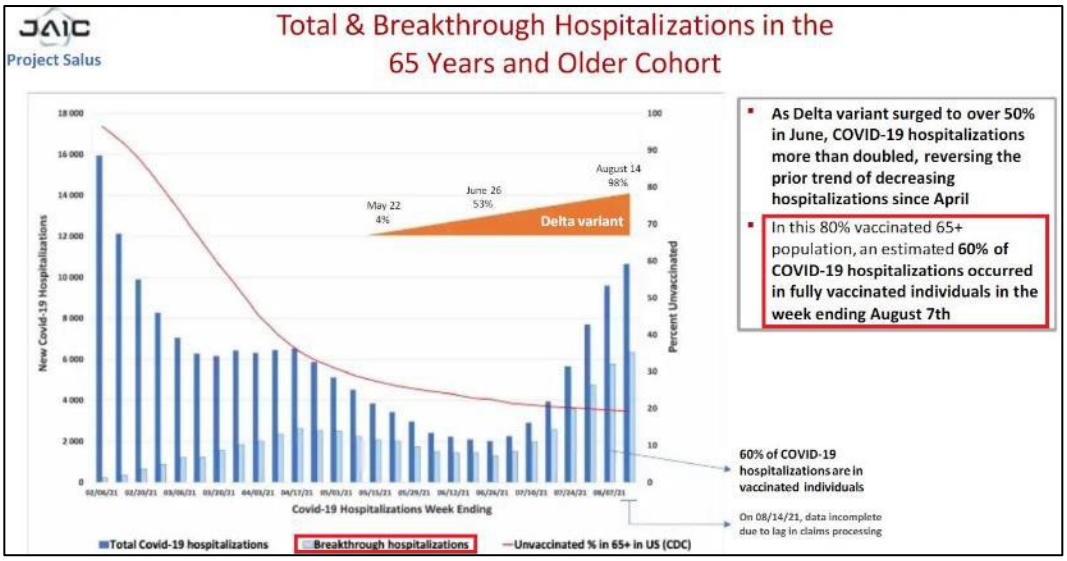
The reality of how safe these vaccines are is absolutely not public… Healthy people who have had adverse reactions after the vaccine, there's been a concerted effort to prevent these types of stories, these experiences, from receiving the attention that they obviously should receive...

It's completely ridiculous. Many Americans can sense that there’s been total dishonesty about the safety of the vaccines.”

[552] ***Effectiveness of mRNA COVID-19 VaccinesAgainst the Delta VariantAmong 5.6M Medicare Beneficiaries 65 Years and Older***
Joint Artificial Intelligence Center (Department of Defense)
October 5, 2021
https://www.scribd.com/document/530559640/Effectiveness-of-mRNA-COVID-19-Vaccines-Against-the-Delta-Variant-Among-5-6M-Medicare-Beneficiaries-65-Years-and-Older

Slide 2: "Breakthrough infections occurring 6 months after vaccination have an **increased risk of hospitalization** (odds ratio = 2.5)"

Note: As stated on Slide 11 (below), "60% of COVID-19 hospitalizations" in the 65+ age group "occurred in fully vaccinated individuals in the week ending August 7th."



[553] **ADDED since 2/8/2022**
Dr. Robert Redfield's shocking admission about vaccine deaths
Dr. Robert Redfield, former Director of the Centers for Disease Control
October 21, 2021
https://rumble.com/vo1sad-dr-robert-redfield-shocking-admission-about-vaccine-deaths.html

Redfield: "I hear a lot of times people feel it's a rare event, that fully vaccinated people may die. I happen to be the senior advisor to Governor Hogan in the state of Maryland, and in the last six to eight weeks, more than 40% of the people who died in Maryland were **fully vaccinated**."

[554] ***COVID-19 vaccine surveillance report, Week 42***
UK Health Security Agency
October 21, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027511/Vaccine-surveillance-report-week-42.pdf

"**Results**: … In individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated…

Table 2. COVID-19 cases by vaccination status between week 38 and week 41 2021

Cases reported by specimen date between week 38 and week 41 2021	Total	Unlinked*	Not vaccinated	Received one dose (1-20 days before specimen date)	Received one dose, ≥21 days before specimen date	Second dose ≥14 days before specimen date	Rates among persons vaccinated with 2 doses (per 100,000)	Rates among persons not vaccinated (per 100,000)
Under 18	397,882	24,292	351,148	10,698	11,001	743	314.1	3,013.6
18-29	62,885	7,512	20,902	758	8,404	25,309	462.1	615.4
30-39	92,257	7,346	21,726	636	6,545	56,004	956.7	751.1
40-49	130,904	7,297	13,022	293	3,800	106,492	1,731.3	772.9
50-59	88,020	4,790	5,399	80	1,632	76,119	1,075.3	528.6
60-69	45,155	2,614	1,872	24	617	40,028	704.1	347.1
70-79	27,360	1,559	658	12	215	24,916	537.9	267.6
≥80	11,907	854	382	7	215	10,449	406.8	304.1

* Individuals whose NHS numbers were unavailable to link to the NIMS

** Interpretation of the case rates in vaccinated and unvaccinated population is particularly susceptible to changes in denominators and should be interpreted with extra caution

… Seropositivity estimates for N antibody will underestimate the proportion of the population previously infected due to… (iii) recent observations from UK Health Security Agency (UKHSA) surveillance data that N antibody levels appear to be **lower in individuals who acquire infection following 2 doses of vaccination** [*emphasis added*]."

[555] ***Public Health Scotland COVID-19 Statistical Report As at 18 October 2021***
Public Health Scotland
October 20, 2021
https://publichealthscotland.scot/media/9821/21-10-20-covid19-publication_report.pdf

Page 48: In Scotland for the period 9/11/2021 through 10/8/2021, Table 20 indicates a total of 96 "COVID-19 related deaths" amongst the unvaccinated and 436 such deaths amongst recipients of two vaccination doses.

Table 20: Number of confirmed COVID-19 related deaths by vaccination status at time of test and age-standardised mortality rate per 100,000, 11 September 2021 to 08 October 2021

Week/Vaccination Status	Unvaccinated		1 Dose		2 Doses	
	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
11 September - 17 September 2021	26	**7.73** (4.47 - 10.98)	4	**5.13** (0.00 - 10.70)	101	**1.94** (1.55 - 2.31)
18 September - 24 September 2021	29	**8.63** (5.19 - 12.06)	8	**14.72** (3.69 - 25.75)	121	**2.37** (1.94 - 2.80)
25 September - 01 October 2021	22	**6.87** (3.71 - 10.03)	4	**8.88** (0.05 - 17.71)	114	**2.22** (1.81 - 2.63)
02 October - 08 October 2021	19	**5.29** (2.62 - 7.97)	0	**0.00** (0.00 - 0.00)	100	**1.96** (1.57 - 2.35)

Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 9. A confirmed COVID-19 related death is defined as an individual who has tested positive by PCR for SARS-CoV-2 at any time point and has COVID-19 listed as an underlying or contributory cause of death on the death certificate. Age-standardised mortality rates per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 9). This definition is for the purposes of evaluating the impact of the COVID-19 vaccine on confirmed COVID-19 deaths. The numbers reported in this section may differ from other published COVID-19 death data. Data are based on date of registration. In Scotland deaths must be registered within 8 days although in practice, the average time between death and registration is around 3 days. More information on days between occurrence and registration can be found on the NRS website.

[556] ***Antibody levels decrease after two doses of Pfizer vaccine – study***
Jerusalem Post
Rossella Tercatin
October 7, 2021
https://www.jpost.com/health-and-wellness/coronavirus/antibody-levels-decrease-after-two-doses-of-pfizer-vaccine-study-681260

"Antibody levels **decrease rapidly** after two doses of the Pfizer coronavirus vaccine [*emphasis added*], a study by researchers at the Sheba Medical Center published Wednesday in the *New England Journal of Medicine* showed…

Over 4,800 staff members of Sheba participated in the study…

'We saw that the decline in antibody level is very rapid,' Regev-Yochay [*one of the study's authors*] said at a press briefing."

[557] ***Waning Immune Humoral Response to BNT162b2 Covid-19 Vaccine over 6 Months***
New England Journal of Medicine (NEJM)
Einav G. Levin, Yaniv Lustig, *et al*.
October 6, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2114583

"**Methods**: We conducted a 6-month longitudinal prospective study involving vaccinated health care workers who were tested monthly for the presence of anti-spike IgG and neutralizing antibodies. Linear mixed models were used to assess the dynamics of antibody levels and to determine predictors of antibody levels at 6 months.

Results: The study included 4868 participants, with 3808 being included in the linear mixed-model analyses. The level of IgG antibodies decreased at a consistent rate, whereas the neutralizing antibody level decreased rapidly for the first 3 months with a relatively slow decrease thereafter…

Conclusions: Six months after receipt of the second dose of the BNT162b2 [*Pfizer*] vaccine, **humoral [*immune*] response was substantially decreased**, especially among men, among persons 65 years of age or older, and among persons with immunosuppression."

[558] ***Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar***
New England Journal of Medicine (NEJM)
Hiam Cernaitelly, Patrick Tang, *et al*.
October 6, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2114114

"**Results**: Estimated BNT162b2 [*Pfizer*] effectiveness against any SARS-CoV-2 infection was negligible in the first 2 weeks after the first dose. It increased to 36.8% (95% confidence interval [CI], 33.2 to 40.2) in the third week after the first dose and reached its peak at 77.5% (95% CI, 76.4 to 78.6) in the first month after the second dose. Effectiveness declined gradually thereafter, with the decline accelerating after the fourth month to reach approximately **20% in months 5 through 7** after the second dose [*emphasis added*]…

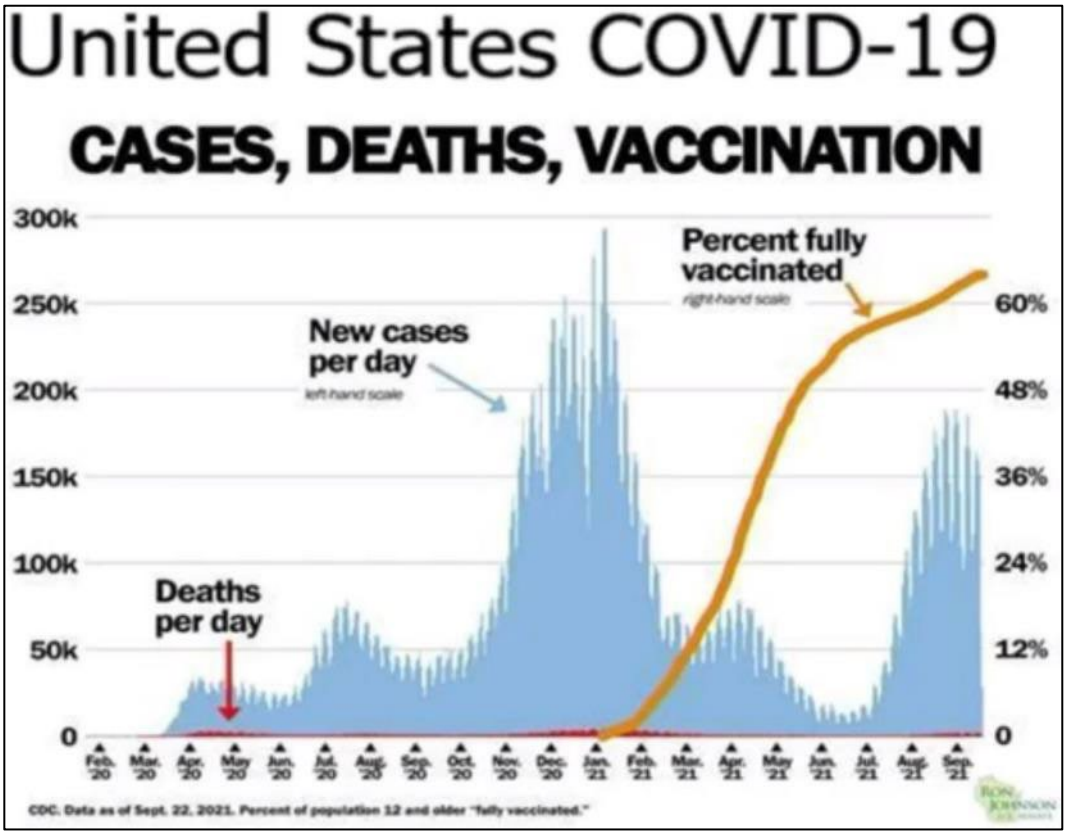
Discussion: … By far the dominant variant during the study was B.1.351 [*beta*], and a **similar pattern of waning of protection** was observed for B.1.1.7 [*alpha*], B.1.351, and B.1.617.2 *delta*] [*emphasis added*]."

[559] ***Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study***
The Lancet
Sara Y. Tartof, Jeff M. Slezak, *et al*.
October 4, 2021
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02183-8/fulltext

"**Background**: Vaccine effectiveness studies have not differentiated the effect of the delta (B.1.617.2) variant and potential waning immunity in observed reductions in effectiveness against SARS-CoV-2 infections. We aimed to evaluate overall and variant-specific effectiveness of BNT162b2 (tozinameran, Pfizer–BioNTech) against SARS-CoV-2 infections and COVID-19-related hospital admissions by time since vaccination among members of a large US health-care system…

Findings: … **Effectiveness against infections declined** from 88% (95% CI 86–89) during the first month after full vaccination to **47% (43–51) after 5 months** [*emphasis added*]. Among sequenced infections, vaccine effectiveness against infections of the delta variant was high during the first month after full vaccination (93% [95% CI 85–97]) but declined to 53% [39–65] after 4 months."

[560] **Video (65m): Dr. Peter McCullough presentation at 78th Annual Meeting of Association of American Physicians and Surgeons (AAPS)**
AAPS
October 2, 2021
https://odysee.com/@alpha:8/Dr-McCullough-78th-AAPS:d



[561] **Correspondence: *Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States***
European Journal of Epidemiology
S.V. Subramarian (Harvard University) and Akhil Kumar (Turner Fenton Secondary School, Ontario)
September 30, 2021
https://link.springer.com/content/pdf/10.1007/s10654-021-00808-7.pdf

"**Findings**: At the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days (Fig. 1). In fact, the trend line suggests a marginally positive association such that **countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people** [*emphasis added*]. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million people in the last 7 days. The lack of a meaningful association between percentage population fully vaccinated and new COVID-19 cases is further exemplified, for instance, by comparison of Iceland and Portugal. Both countries have over 75% of their population fully vaccinated and have more COVID-19 cases per 1 million people than countries such as Vietnam and South Africa that have around 10% of their population fully vaccinated.

Across the US counties too, the median new COVID-19 cases per 100,000 people in the last 7 days is largely similar across the categories of percent population fully vaccinated (Fig. 2). Notably there is also substantial county variation in new COVID-19 cases within categories of percentage population fully vaccinated. There also appears to be no significant signaling of COVID-19 cases decreasing with higher percentages of population fully vaccinated (Fig. 3).

Of the top 5 [US] counties that have the highest percentage of population fully vaccinated (99.9–84.3%), the US Centers for Disease Control and Prevention (CDC) identifies 4 of them as **'High' Transmission counties** [*emphasis added*]. Chattahoochee (Georgia), McKinley (New Mexico), and Arecibo (Puerto Rico) counties have above 90% of their population fully vaccinated with all three being classified as 'High' transmission. Conversely, of the 57 counties that have been classified as 'low' transmission counties by the CDC, 26.3% (15) have percentage of population fully vaccinated below 20%."

Interpretation: … [I]n a report released from the Ministry of Health in Israel, the **effectiveness of 2 doses of the BNT162b2 (Pfizer-BioNTech) vaccine against preventing COVID-19 infection was reported to be 39%**, substantially lower than the trial efficacy of 96% [*emphasis added*]. It is also emerging that immunity derived from the Pfizer-BioNTech vaccine may not be as strong as immunity acquired through recovery from the COVID-19 virus. A substantial decline in immunity from mRNA vaccines 6-months post immunization has also been reported. Even though vaccinations offers protection to individuals against severe hospitalization and death, the CDC reported an increase from 0.01 to 9% and 0 to 15.1% (between January to May 2021) in the rates of hospitalizations and deaths, respectively, amongst the fully vaccinated "

[562] ***Durability of immune responses to the BNT162b2 mRNA vaccine***
National Institutes of Health (NIH), Stanford University, and Emory University
Mehul S. Suthar, Prabhu S. Arunachalam, *et al*.
September 30, 2021
https://www.biorxiv.org/content/10.1101/2021.09.30.462488v1.full

"**Abstract**: … Here, we analyzed antibody responses to the homologous Wu strain as well as several variants of concern, including the emerging Mu (B.1.621) variant, and T cell responses in a subset of these volunteers at six months (day 210 post-primary vaccination) after the second dose. Our data demonstrate a **substantial waning of antibody responses** and **T cell immunity** to SARS-CoV-2 and its variants, at 6 months following the second immunization with the BNT162b2 vaccine [*emphasis added*]. Notably, a significant proportion of vaccinees have neutralizing titers below the detection limit, and suggest a 3rd booster immunization might be warranted to enhance the antibody titers and T cell responses"

[563] ***Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021***
Eurosurveillance
Pnina Shitrit, Neta S Zuckerman, Orna Mor, Bat-Sheva Gottesman, and Michal Chowers
September 30, 2021
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100822#html_fulltext

> "We present an investigation of a coronavirus disease (COVID-19) outbreak that started from one unidentified COVID-19 patient, with extensive, rapid nosocomial spread among vaccinated, including individuals wearing surgical masks.
>
> **Setting**: Meir Medical Center has 780 beds, most rooms accommodate three to four patients, 1 m apart with separation curtain partitions between beds. Starting in March 2020, patients have been encouraged to wear surgical masks. Although use was inconsistent, it was enforced during patient–staff encounters for both sides. On the dedicated COVID-19 ward, dedicated staff members worked with full personal protective equipment (PPE): N-95 mask, face shield, gown, gloves and hair cover…
>
> **Demographic and clinical information:** Of the 42 cases diagnosed in this outbreak, **38 were fully vaccinated** with two doses of the Comirnaty vaccine, one was recovered with one vaccination and three were unvaccinated… Twenty-three were patients, 16 staff members and three family members… Among the patients (median age: 77 years; range: 42–93; median time from second vaccine dose to infection: 176 days; range: 143-188), **eight became severely ill, six critically ill** and **five of the critically ill died** [*emphasis added*].
>
> **Discussion**: … [T]his communication emphasises several points. It challenges the assumption that high universal vaccination rates will lead to herd immunity and prevent COVID-19 outbreaks. This was probably true for the wild-type SARS-CoV-2 virus, but in the outbreak described here, 96.2% of the exposed population was vaccinated. Infection advanced rapidly (many cases became symptomatic within 2 days of exposure), and viral load was high. Another accepted view is that, when facing a possible mismatch between the SARS-CoV-2 variant and vaccine or waning immunity, the combination of vaccine and face mask should provide the necessary protection. Although some transmission between staff members could have occurred without masks, all transmissions between patients and staff occurred between masked and vaccinated individuals, as experienced in an outbreak from Finland."

[564] ***The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission***
University of Oxford and the Department of Health and Social Care (UK)
David W. Eyre, Donald Taylor, *et al*.
September 29, 2021
https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1.full-text

> "**Methods**: We performed a retrospective observational cohort study of contacts of SARS-CoV-2-infected index cases using contact testing data from England.

Results: … Transmission reductions declined over time since second vaccination, for Delta reaching similar levels to unvaccinated individuals by 12 weeks for ChAdOx1 and attenuating substantially for BNT162b2. Protection from vaccination in contacts also declined in the 3 months after second vaccination.

Duration of protection and transmission reductions

[H]igher probabilities of PCR-positive results in contacts 14 days after second vaccination for Delta vs. Alpha meant that by 12 weeks post second ChAdOx1 dose there was **no evidence that onward Delta transmission rates differed between those not vaccinated and those having received two ChAdOx1 doses** and the impact of BNT162b2 had also attenuated substantially."

[565] ***No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant***
University of California- Davis, -Berkeley, and -San Francisco
Charlotte B. Acharya, John Schrom, *et al*.
September 29, 2021
https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v1

"**Discussion**: In our study, mean viral loads as measured by Ct-value were similar for large numbers of asymptomatic and symptomatic individuals infected with SARS-Cov-2 during the Delta surge, regardless of vaccine status, age, or gender… Our study is consistent with other recent reports showing similar viral loads among vaccinated and unvaccinated individuals in settings with transmission of the Delta variant."

[566] ***Sharp decline in antibody levels after seven months for double vaccinated***
Sveriges Television (SVT), Swedish public television
Josefin Lennen Merckx
September 28, 2021
https://www.svt.se/nyheter/inrikes/kraftig-nedgang-i-antikroppsnivaer-efter-sju-manader-for-dubbelvaccinerade

"In total, more than 2,000 healthcare workers are included in the COMMUNITY study. The goal is to learn more about immunity after COVID-19 and about the effects of vaccines.

The latest interim report of 464 people shows how quickly antibody levels have slowed down in double vaccinated people who have not had COVID.

For Pfizer vaccinated, antibody levels halved after three months.

After seven months, only 15% of the original levels remained – a **decrease of as much as 85%** [*emphasis added*].

'It is fully expected that antibody levels will drop over time, but I am surprised that it has dropped so significantly in such a relatively healthy and young group,' says Charlotte Thålin...

Since the staff who received Astra Zeneca's vaccine received the second dose later, the researchers have only been able to follow them for three months. But the decline was even greater. After three months, Astravaccinated had only one-fifth of pfizer vaccine antibody levels."

[567] ***Covid-19 in Wales: A third of positive cases are unvaccinated***
BBC News
September 24, 2021
https://www.bbc.com/news/uk-wales-58680204

> "Nearly 13% of hospital patients with confirmed Covid were unvaccinated.
>
> PHW said the vaccines had helped keep Covid hospital numbers much lower during the third wave.
>
> Although 80% of patients have been double-dosed with a vaccine, public health officials said this is not evidence that the vaccine is not working…"

[568] ***SARS-CoV-2 variants of concern and variants under investigation in England – Technical briefing 23***
Public Health England
September 17, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1018547/Technical_Briefing_23_21_09_16.pdf

> **Note**: All figures below are taken from p. 18, 'Table 5. Attendance to emergency care and deaths of sequenced and genotyped Delta cases in England by vaccination status (1 February 2021 to 12 September 2021).'
>
> **593,572 Total Delta cases**. Of this number:
>
> - 26.5% were diagnosed at least 14 days after their second inoculation (157,400 / 593,572)
> - 43.4% were 'unvaccinated' (257,357 / 593,572)
>
> **2,542 Total deaths within 28 days of positive specimen date**. Of this number:
>
> - **63.5%** were diagnosed at least 14 days after their second inoculation (1,613 / 2,542)
> - **28.4%** were 'unvaccinated' (722 / 2,542) [*emphasis added*]

[569] ***COVID vaccine immunity is waning — how much does that matter?***
Nature magazine
Elie Dolgin
September 17, 2021
https://www.nature.com/articles/d41586-021-02532-4

> "Immunological studies have documented a steady decline of antibody levels among vaccinated individuals. Long-term follow-up of vaccine trial participants has revealed a growing risk of breakthrough infection. And health-care records from countries such as Israel, the United Kingdom and elsewhere all show that COVID-19 vaccines are losing their strength, at least when it comes to keeping a lid on transmissible disease.
>
> That's without accounting for the Delta threat either — and it's clear that vaccine–induced antibodies do a worse job at recognizing SARS-CoV-2 variants compared with the ancestral strain of the virus4. What remains unclear, however, is to what degree the immune system's

safeguards that protect vaccinated people against severe disease, hospitalization and death might be fading as well."

[570] **Commentary: *Shockingly, CDC Now Lists Vaccinated Deaths as Unvaccinated***
Joseph Mercola
September 16, 2021
https://www.lewrockwell.com/2021/09/joseph-mercola/shockingly-cdc-now-lists-vaccinated-deaths-as-unvaccinated/

"**How CDC Counts Breakthrough Cases**: According to the CDC, you're not counted as fully vaccinated until a full 14 days have passed since your second injection in the case of Pfizer or Moderna, or 14 days after your first dose of Janssen. This is how the CDC defines a vaccine breakthrough case:

'… a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after they have completed all recommended doses of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine.'

In other words, if you've received one dose of Pfizer or Moderna and develop symptomatic COVID-19, get admitted to the hospital and/or die from COVID, you're counted as an unvaccinated case. If you've received two doses and get ill within 14 days, you're still counted as an unvaccinated case…

Different Testing Guidelines for Vaxxed and Unvaxxed: It's not just the CDC's definition of a breakthrough case that skews the data. Even more egregious and illogical is the fact that the CDC even has two different sets of testing guidelines — one for vaccinated patients and another for the unvaccinated.

Since the beginning of the pandemic, the CDC has recommended a PCR test cycle threshold (CT) of 40. This flies in the face of scientific consensus, which has long been that a CT over 35 will produce 97% false positives, essentially rendering the test useless.

In mid-May 2021, the CDC finally lowered its recommended CT count, but only for patients who have received one or more COVID shots. So, if you have received a COVID injection, the CDC's guidelines call for your PCR test to be run at a CT of 28 or less. If you are unvaccinated, your PCR test is to be run at a CT of 40, which grossly overestimates the true prevalence of infection.

The end result is that unvaccinated individuals who get tested are FAR more prone to get false positives, while those who have received the jab are more likely to get an accurate diagnosis of infection."

[571] ***Health Ministry chief says coronavirus spread reaching record heights***
The Times of Israel
Stuart Winer
September 14, 2021
https://www.timesofisrael.com/health-ministry-chief-says-coronavirus-spread-reaching-record-heights/

> "Health Ministry Director-General Nachman Ash said Tuesday that the current wave of coronavirus infections is surpassing anything seen in previous outbreaks and that he is disappointed that a recent downward trend appeared to be reversing.
>
> Ash's remarks via video call to the Knesset Constitution, Law, and Justice Committee came as Health Ministry figures showed that over 10,000 new COVID-19 cases were diagnosed the day before and that the positive test rate was climbing.
>
> Pointing out that there is an average of 8,000 new infections each day, with occasional peaks over 10,000, he said, 'That is a record that did not exist in the previous waves,' including the massive third wave at the end of last year."

[572] ***The COVID-19 Hospitalization Metric in the Pre- and Post-vaccination Eras as a Measure of Pandemic Severity: A Retrospective, Nationwide Cohort Study***
Boston Healthcare System
Nathanael Fillmore, Jennifer La, *et al*.
September 13, 2021
https://assets.researchsquare.com/files/rs-898254/v1/f2800895-4df3-4945-85ae-c1be66aaca23.pdf?c=1631889328

> "**Setting**: Multi-center, nationwide study conducted in the healthcare system of the US Department of Veterans Affairs (VA) from March 1, 2020, through June 30, 2021...
>
> **Exposure**: SARS-CoV-2 vaccination status at the time of hospitalization. Patients were regarded as fully vaccinated starting 14 days after receiving the second of a 2-dose regimen or 14 days after receipt of a single-dose vaccine.
>
> **Results**: … Among 15,196 admissions on or after 1/21/2021 (**unvaccinated, 11,569; vaccinated, 3,627**), 7,908 met the case definition for moderate-to-severe disease (**unvaccinated, 6,362; vaccinated, 1,546**)."

[573] ***Covid-19 Vaccine Mandates Are Now Pointless: Covid-19 vaccines do not keep people from catching the prevailing Delta variant and passing it to others***
Nina Pierpont, MD, PhD
September 9, 2021
https://theexpose.uk/wp-content/uploads/2021/09/Pierpont-Why-mandated-vaccines-are-pointless-final-1.pdf

> "These three different studies in three countries with three different population sampling methods produced the same result: with the current, dominant Delta strain, vaccinated people become infected and carry just as much infectious virus in their upper respiratory tracts when infected as unvaccinated people. The reproducibility of this finding makes it a very strong finding…

Blaming the unvaccinated for the rapid spread of the Delta variant has no merit whatsoever, since both vaccinated and unvaccinated infected people are equally infectious to others, and vaccinated and unvaccinated people are represented in illness samples in proportion to their representation in the general population, showing they are equally likely to become infected."

[574] ***Hospitalisation among vaccine breakthrough COVID-19 infections***
Infectious Diseases – The Lancet (Yale School of Medicine)
Prerak V. Juthani, Akash Gupta, *et al*.
September 7, 2021
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00558-2/fulltext

"We did a systematic review of patients admitted to hospital with SARS-CoV-2 (confirmed by a positive PCR test at the time of admission) between March 23 and July 1, 2021… Patients were considered fully vaccinated if the final dose (either second dose of BNT162b2 or mRNA-1273, or first dose of Ad.26.COV2.S) was administered at least 14 days before symptom onset or a positive PCR test for SARS-CoV-2…

Patients deemed to have a breakthrough SARS-CoV-2 infection—ie, the 54 patients who were fully vaccinated—were evaluated for illness severity. Among this cohort, we found that 25 (46%) patients were asymptomatic (admitted to hospital for a non-COVID-19-related diagnosis but with an incidental positive PCR test for SARS-CoV-2), four (7%) had mild disease, 11 (20%) had moderate disease, and 14 (26%) had severe or critical illness."

[575] ***The Oxford/AstraZeneca COVID-19 vaccine: what you need to know***
World Health Organization
September 2, 2021
https://www.who.int/news-room/feature-stories/detail/the-oxford-astrazeneca-covid-19-vaccine-what-you-need-to-know

"**How efficacious is the vaccine?** The AZD1222 vaccine against COVID-19 has an efficacy of 63.09% against symptomatic SARS-CoV-2 infection."

[576] ***Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK***
University of Oxford
August 2021
https://www.ndm.ox.ac.uk/files/coronavirus/covid-19-infection-survey/finalfinalcombinedve20210816.pdf

"**Abstract**: … With Delta, infections occurring following two vaccinations had similar peak viral burden to those in unvaccinated individuals."

[577] ***Waning immunity of the BNT162b2 vaccine: A nationwide study from Israel***
Israel Ministry of Health
Yair Goldberg, Micha Mandel, *et al*.
August 30, 2021
https://www.medrxiv.org/content/10.1101/2021.08.24.21262423v1.full-text

"**Background**: Starting December 2020, Israel began a mass vaccination campaign against coronavirus administering the Pfizer BNT162b2 vaccine, which led to a sharp curtailing of the outbreak. After a period with almost no SARS-CoV-2 infections, a resurgent COVID-19 outbreak initiated mid June 2021. Possible reasons for the breakthrough were reduced vaccine effectiveness against the Delta variant, and waning immunity. The aim of this study was to quantify the extent of waning immunity using Israel's national-database…

Results: The rates of both documented SARS-CoV-2 infections and severe COVID-19 exhibit a statistically significant increase as time from second vaccine dose elapsed. Elderly individuals (60+) who received their second dose in March 2021 were 1.6 (CI: [1.3, 2]) times more protected against infection and 1.7 (CI: [1.0, 2.7]) times more protected against severe COVID-19 compared to those who received their second dose in January 2021. Similar results were found for different age groups.

Conclusions: These results indicate a strong effect of waning immunity in all age groups after six months [*emphasis added*]."

[578] ***'Majority' of those dying have had both jabs***
The Scottish Mail
Gareth Rose
August 29, 2021
https://www.pressreader.com/uk/the-scottish-mail-on-sunday/20210829/282183654147043

"The vast majority of Scots now dying from Covid are fully vaccinated, figures show. Three quarters of those who died in the most recent week for which data was available had received both doses…

Public Health Scotland does not directly publish weekly figures of vaccinated and unvaccinated deaths. But this paper has calculated in the month up to August 12, 144 out of 236 deaths were of people with both doses, compared with 80 unvaccinated, and 12 with just one dose."

[579] ***Significant proportions of people admitted to hospital, or dying from covid-19 in England are vaccinated—this doesn't mean the vaccines don't work***
British Medical Journal
Kit Yates
August 25, 2021
https://blogs.bmj.com/bmj/2021/08/25/significant-proportions-of-people-admitted-to-hospital-or-dying-from-covid-19-in-england-are-vaccinated-this-doesnt-mean-the-vaccines-dont-work/

> "More vaccinated people are dying of the delta variant of covid than unvaccinated people, according to a recent report from Public Health England. The report shows that 489 of 742 people (65.9%) who died of the delta variant within 28 days of a positive covid test between 1 February 2021 and 2 August 2021, had received at least one dose of the vaccine. 54.1% (402 of 742) had received both doses."

[580] ***Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant***
University of Wisconsin-Madison
Kasen K. Riemersma, Brittany E. Grogan, *et al*.
August 24, 2021
https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v1.full.pdf

> "**Abstract**: … Understanding how and why the virus is spreading in settings where there is high vaccine coverage has important public health implications. It is particularly important to assess whether vaccinated individuals who become infected can transmit SARS-CoV-2 to others… We find **no difference in viral loads** when comparing unvaccinated individuals to those who have vaccine 'breakthrough' infections [*emphasis added*]. Furthermore, individuals with vaccine breakthrough infections frequently test positive with viral loads consistent with the ability to shed infectious viruses…"

[581] ***Does the FDA think these data justify the first full approval of a covid-19 vaccine?***
British Medical Journal
Peter Doshi
August 23, 2021
https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/

> "[T]he recent reports from Israel's Ministry of Health caught my eye. In early July, they reported that efficacy [*of the Pfizer product*] against infection and symptomatic disease 'fell to 64%.' By late July, **it had fallen to 39%** where Delta is the dominant strain. This is very low. For context, the FDA's expectation is of 'at least 50%' efficacy for any approvable vaccine [*emphasis added*].
>
> Now Israel, which almost exclusively used Pfizer vaccine, has begun administering a third "booster" dose to all adults over 40. And starting 20 September 2021, the US plans to follow suit for all 'fully vaccinated' adults eight months past their second dose…
>
> Enter Pfizer's preprint. As an RCT reporting 'up to six months of follow-up,' it is notable that evidence of waning immunity was already visible in the data by the 13 March 2021 data cut-off."

[582] ***Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence***
nference and Mayo Clinic
Arjun Puranik, Patrick J. Lenehan, *et al*.
August 21, 2021
https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v3.full-text

> "In July, vaccine effectiveness against hospitalization has remained high (mRNA-1273: 81%, 95% CI: 33-96.3%; BNT162b2: 75%, 95% CI: 24-93.9%), but effectiveness against infection was lower for both vaccines (mRNA-1273: **76%**, 95% CI: 58-87%; BNT162b2: **42%**, 95% CI: 13-62%) [*emphasis added*], with a more pronounced reduction for BNT162b2."

[583] ***Chris Whitty warns of 'very sick' Covid patients as he urges people to get a jab***
Evening Standard
Aine Fox
August 20, 2021
https://www.standard.co.uk/news/uk/england-delta-donald-trump-government-public-health-england-b951620.html

> According to Public Health England, as of August 15, 2021: "Of the 113 deaths of people under 50, 72 (64%) were unvaccinated, 11 (10%) had received one jab and 27 (24%) had received both. Of the 3,173 people aged 50 or over admitted to hospital in England up to the middle of this month who were either confirmed or likely to have had the Delta variant, 989 (31%) were not jabbed. A total of 318 (10%) had received one dose of vaccine and **1,838 (58%) had received two** [*emphasis added*]."

[584] ***Significant reduction in humoral immunity among healthcare workers and nursing home residents 6 months after COVID-19 BNT162b2 mRNA vaccination***
Case Western Reserve School of Medicine
David H. Canaday, Oladayo A. Oyebanji, *et al*.
August 20, 2021
https://www.medrxiv.org/content/10.1101/2021.08.15.21262067v3.full-text

> "**Abstract**: High COVID-19 mortality among nursing home (NH) residents led to their prioritization for SARS-CoV-2 vaccination; most NH residents received BNT162b2 mRNA vaccination under the Emergency Use Authorization due to first to market and its availability. With NH residents' poor initial vaccine response, the rise of NH breakthrough infections and outbreaks, characterization of the durability of immunity to inform public health policy on the need for boosting is needed. We report on humoral immunity from 2 weeks to 6-months post-vaccination in 120 NH residents and 92 ambulatory healthcare worker controls with and without pre-vaccination SARS-CoV-2 infection. Anti-spike and anti-receptor binding domain (RBD) IgG, and serum neutralization titers, were assessed using a bead-based ELISA method and pseudovirus neutralization assay. **Anti-spike, anti-RBD and neutralization levels dropped more than 84% over 6 months' time in all groups** irrespective of prior SARS-CoV-2 infection [*emphasis added*]."

[585] ***The CDC Only Tracks a Fraction of Breakthrough COVID-19 Infections, Even as Cases Surge***
ProPublica
Jenny Deam and Bianca Fortis
August 20, 2021
https://www.propublica.org/article/the-cdc-only-tracks-a-fraction-of-breakthrough-covid-19-infections-even-as-cases-surge

> "A May 1 decision by the CDC to **only track breakthrough infections that lead to hospitalization or death** has left the nation with a muddled understanding of COVID-19's impact on the vaccinated [*emphasis added*] …
>
> Today there remains no full understanding on how the aggressively contagious delta variant spreads among the nearly 200 million partially or fully vaccinated Americans like Ingram, or on how many are getting sick.
>
> The nation is flying blind yet again, critics say, because on May 1 of this year — as the new variant found a foothold in the U.S. — the Centers for Disease Control and Prevention mostly stopped tracking COVID-19 in vaccinated people, also known as breakthrough cases, unless the illness was severe enough to cause hospitalization or death."

[586] ***COVID vaccines protect against Delta, but their effectiveness wanes***
Nature
Katharine Sanderson
August 19, 2021
https://www.nature.com/articles/d41586-021-02261-8

> "Researchers at the University of Oxford, UK, and the country's Office for National Statistics analysed a vast data set comprising the results of 2,580,021 PCR tests…
>
> The vaccine developed by Oxford and the pharmaceutical company AstraZeneca in Cambridge, UK, was 69% effective against a high viral load 14 days after the second dose, falling to 61% by 90 days."

[587] ***Covid-19: Fully vaccinated people can carry as much delta virus as unvaccinated people, data indicate***
British Medical Journal
Shaun Griffin
August 19, 2021
https://www.bmj.com/content/374/bmj.n2074

> "Adults who have been fully vaccinated against SARS-CoV-2 can carry the same viral load of the delta variant as those who are unvaccinated, a preliminary analysis of UK data suggests."

[588] ***Over 12,000 breakthrough COVID-19 cases reported in Massachusetts as of August 14***
WWLP News
Colin A. Young
August 17, 2021
https://www.wwlp.com/news/massachusetts/over-12000-breakthrough-covid-19-cases-reported-in-massachusetts-as-of-august-14/

> "In the week from Aug. 7 to Aug. 14, DPH counted 2,672 new breakthrough infections, about a 20 percent increase over the 2,232 breakthrough infections reported the previous week… The 2,672 newly-reported breakthrough cases represent nearly 40 percent of the state's recent one-week total of new cases… (The Massachusetts Department of Public Health) cautioned Tuesday that there are probably more breakthrough infections and hospitalizations among fully vaccinated people than it counts and can report."

[589] ***A grim warning from Israel: Vaccination blunts, but does not defeat Delta***
Science magazine
Meredith Wadman
August 16, 2021
https://www.science.org/news/2021/08/grim-warning-israel-vaccination-blunts-does-not-defeat-delta

> "What is clear is that 'breakthrough' cases are not the rare events the term implies. As of 15 August, 514 Israelis were hospitalized with severe or critical COVID-19, a 31% increase from just 4 days earlier. Of the 514, 59% were fully vaccinated. Of the vaccinated, 87% were 60 or older. 'There are so many breakthrough infections that they dominate and most of the hospitalized patients are actually vaccinated,' says Uri Shalit, a bioinformatician at the Israel Institute of Technology (Technion) who has consulted on COVID-19 for the government…
>
> Yet boosters are unlikely to tame a Delta surge on their own, says Dvir Aran, a biomedical data scientist at Technion. In Israel, the current surge is so steep that 'even if you get two-thirds of those 60-plus [boosted], it's just gonna give us another week, maybe 2 weeks until our hospitals are flooded.'"

[590] ***COVID cabinet approves new restrictions as cases soar***
Jerusalem Post
Maayan Jaffe-Hoffman
August 12, 2021
https://www.jpost.com/israel-news/israel-hits-400-serious-covid-cases-ahead-of-corona-cabinet-meeting-676412

> "On Wednesday morning, the Health Ministry reported 694 people were being treated in Israeli hospitals for the virus, among them 400 in serious condition, with **64% of those patients defined as serious cases being fully vaccinated**, compared with 32% who were not [*emphasis added*]."

[591] ***SARS-CoV-2 variants of concern and variants under investigation in England***
Public Health England
August 6, 2021
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1009243/Technical_Briefing_20.pdf

From p. 18 (Table 5. Attendance to emergency care and deaths of confirmed and provisional Delta cases in England by vaccination status):

- Total number of unvaccinated cases: 151,054
- Total number of unvaccinated fatalities: 253 (205 + 48)
- Total number of double-vaccinated cases (i.e., people having received 2 CV shots): 47,008
- Total number of double-vaccinated fatalities: 402

Note: Based on these figures, the Case Fatality Rates for this sample population would appear to be as follows (please do your own math):

CFR for unvaccinated cases: 0.167% ([253/151,054] * 100), or 1 in 599

CFR for double-vaccinated cases: 0.855% ([402/47,008] * 100), or 1 in 117

[592] ***Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021***
Morbidity and Mortality Weekly Report
Catherine M. Brown, Johanna Vostok, *et al*.
August 6, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e2-H.pdf

"**What is added by this report?** In July 2021, following multiple large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; **346 (74%) occurred in fully vaccinated persons** [*emphasis added*]. Testing identified the Delta variant in 90% of specimens from 133 patients. Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not."

[593] ***Israel's Public Health Chief Says Evidence Points to Waning COVID Vaccine Immunity***
Haaretz
Ben Samuels
August 1, 2021
https://www.haaretz.com/israel-news/coronavirus-delta-variant-is-50-percent-more-infectious-israeli-top-official-says-1.10068650

"Dr. Sharon Alroy-Preis, Israel's director of public health services, said Sunday that evidence points to the waning immunity in the COVID-19 vaccine... She added that 50 percent of the current infections are vaccinated individuals. 'Previously we thought that fully vaccinated individuals are protected, but we now see that vaccine effectiveness is roughly 40 percent.'"

[594] ***Correlation of SARS-CoV-2 Breakthrough Infections to Time-from-vaccine; Preliminary Study***
KI Research Institute, KSM Research and Innovation Center (Israel)
Barak Mizrahi, Roni Lotan, *et al*.
July 31, 2021
https://www.medrxiv.org/content/10.1101/2021.07.29.21261317v1.full-text

> "**Abstract**: … Leveraging the centralized computerized database of Maccabi Healthcare Services (MHS), we assessed the correlation between time-from-vaccine and incidence of breakthrough infection. We found that the risk for infection was significantly higher for early vaccinees compared to those vaccinated later…
>
> **Main**: Individuals who were vaccinated in January 2021 had a 2.26-fold increased risk (CI 1.80-3.01) for breakthrough infection compared to individuals who were vaccinated in April 2021 (Figure 1).
>
> In this cohort of MHS members, all of whom are vaccinated with the BioNTech/Pfizer mRNA BNT162b2 vaccine in a two-dose regimen, we identified a significant correlation between time-from-vaccine and afforded protection against SARS-CoV-2 infection. The risk for breakthrough infection was significantly higher for early vaccinees compared to those vaccinated later."

[595] ***CDC Scaled Back Hunt for Breakthrough Cases Just as the Delta Variant Grew***
Bloomberg
Drew Armstrong, Rebecca Torrence, and Fiona Rutherford
July 30, 2021
https://www.bloomberg.com/news/articles/2021-07-30/cdc-scaled-back-hunt-for-breakthrough-cases-just-as-the-delta-variant-grew

> "While the Centers for Disease Control and Prevention stopped comprehensively tracking what are known as vaccine breakthrough cases in May, the consequences of that choice are only now beginning to show.
>
> At the time, the agency had identified only 10,262 cases across the U.S. where a fully vaccinated person had tested positive for Covid. But in the months since, the number of vaccine breakthrough cases has grown, as has the risk that they present. And while the CDC has stopped tracking such cases, many states have not. Bloomberg gathered data from 35 states and identified **111,748 vaccine breakthrough cases** through the end of July [*emphasis added*], more than 10 times the CDC's end-of-April tally."

[596] ***Improving communications around vaccine breakthrough and vaccine effectiveness***
Centers for Disease Control and Prevention (CDC)
July 29, 2021
https://context-cdn.washingtonpost.com/notes/prod/default/documents/54f57708-a529-4a33-9a44-b66d719070d9/note/753667d6-8c61-495f-b669-5308f2827155.#page=1

> Slide 3: "At current incidence, **35,000 symptomatic infections per week** among 162 million vaccinated Americans [*emphasis added*]."
>
> Slide 22: "Breakthrough infections may be as transmissible as unvaccinated cases"

[597] ***UK scientists back Covid boosters as study finds post-jab falls in antibodies***
The Guardian
Ian Sample
July 22, 2021
https://www.theguardian.com/world/2021/jul/22/uk-scientists-back-covid-boosters-as-study-finds-post-jab-falls-in-antibodies

> "The UCL Virus Watch study found that antibodies generated by two doses of the Oxford/AstraZeneca and Pfizer/BioNTech vaccines started to wane as early as six weeks after the second shot, in some cases falling more than 50% over 10 weeks."

[598] **Correspondence: *Spike-antibody waning after second dose of BNT162b2 or ChAdOx1***
The Lancet
Madhumita Shrotri, Annalan M D Navaratnam, *et al*.
July 15, 2021
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01642-1/fulltext

> "A significant trend of declining S-antibody levels was seen with time for both ChAdOx1 ($p<0·001$) and BNT162b2 ($p<0·001$; figure; appendix), with levels reducing by about five-fold for ChAdOx1, and by about two-fold for BNT162b2, between 21–41 days and 70 days or more after the second dose. This trend remained consistent when results were stratified by sex, age, and clinical vulnerability (appendix). For BNT162b2, S-antibody levels reduced from a median of 7506 U/mL (IQR 4925–11 950) at 21–41 days, to 3320 U/mL (1566–4433) at 70 or more days. For ChAdOx1, S-antibody levels reduced from a median of 1201 U/mL (IQR 609–1865) at 0–20 days to 190 U/mL (67–644) at 70 or more days…
>
> Our data suggest waning of S-antibody levels in infection-naive individuals over a 3–10-week period after a second dose of either ChAdOx1 or BNT162b2… "

[599] ***Natural infection vs vaccination: Which gives more protection?***
Arutz Sheva
David Rosenberg
July 13, 2021
https://www.israelnationalnews.com/News/News.aspx/309762

> "Nearly 40% of new COVID patients were vaccinated - compared to just 1% who had been infected previously.
>
> Coronavirus patients who recovered from the virus were far less likely to become infected during the latest wave of the pandemic than people who were vaccinated against COVID, according to numbers presented to the Israeli Health Ministry…
>
> Health Ministry data on the wave of COVID outbreaks which began this May show that Israelis with immunity from natural infection were far less likely to become infected again in comparison to Israelis who only had immunity via vaccination…
>
> With a total of 835,792 Israelis known to have recovered from the virus, the 72 instances of reinfection amount to 0.0086% of people who were already infected with COVID. By contrast, Israelis who were vaccinated were **6.72 times more likely to get infected after the shot than after natural infection** [*emphasis added*]."

[600] ***An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland, May 2021***
Eurosurveillance
Iivo Hetemäki, Sohvi Kääriäinen, *et al*.
July 2021
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.30.2100636

> "We describe here an outbreak caused by the Delta variant that originated from one inpatient in a secondary care hospital and spread within the hospital and to three primary care facilities; we describe our experiences in controlling it. Cases were detected among patients, healthcare workers (HCW) and in the community. Both symptomatic and asymptomatic infections were found among vaccinated HCW, and secondary transmission occurred from those with symptomatic infections despite use of personal protective equipment (PPE)…
>
> In conclusion, this outbreak demonstrated that, **despite full vaccination and universal masking of HCW**, breakthrough infections by the Delta variant via symptomatic and asymptomatic HCW occurred [*emphasis added*], causing nosocomical infections. As the Delta variant continues to spread in Europe, we suggest that utilization of FFP2/3 respirators while treating COVID-19 patients should be included in national guidelines."

[601] ***Hospital manager: "Over 90% of our patients are vaccinated, the vaccine wears off in front of our eyes"***
Maariv
July 2021
https://www.maariv.co.il/corona/corona-israel/Article-855728

> "The director of Herzog Hospital in Jerusalem, Dr. Kobi Habib, spoke today (Tuesday) with Anat Davidov on her program… 'Most of our patients are adults over the age of 70, but not only, over 90% of them are vaccinated.' He added, 'There is less good news, which is that the vaccine is quite dissipating in front of our eyes and it becomes less and less effective over time.'"

[602] ***Transmission of SARS-CoV-2 variant B.1.1.7 among vaccinated health care workers***
Infectious Diseases (University Hospital of Heraklion, Greece)
Petros Ioannou, Stamatis Karakonstantis, *et al*.
June 26, 2021
https://www.tandfonline.com/doi/full/10.1080/23744235.2021.1945139

> "**Background**: … The aim of this study was to compare viral load, clinical presentation at diagnosis and type of exposure among vaccinated (with BNT162b2) and non-vaccinated healthcare workers (HCWs)…
>
> **Results**: During the study period 55 HCWs were found positive for SARS-CoV-2, most of whom (44/55) were identified from March 28 to April 14 during an in-hospital COVID-19 outbreak. Of the 55 HCWs, 21 were fully vaccinated and another three had received one dose. Most cases (54/55) were due to variant B.1.1.7. Vaccinated and unvaccinated HCWs did not differ significantly in regards to age, gender, site of acquisition, **presence of symptoms at diagnosis and viral load** [*emphasis added*].

Conclusions: This study found a similar viral load in vaccinated and non-vaccinated HCWs infected by SARS-CoV-2 variant B.1.1.7, suggesting potentially reduced efficacy of BNT162b2 in preventing transmission of B.1.1.7."

[603] ***COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021***
Centers for Disease Control and Prevention
May 25, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7021e3-H.pdf

"A total of **10,262 SARS-CoV-2 vaccine breakthrough infections** had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, **995 (10%) patients were known to be hospitalized**, and **160 (2%) patients died** [*emphasis added*]."

[604] ***Israeli data shows South African variant able to 'break through' Pfizer vaccine***
The Times of Israel
Nathan Jeffay
April 10, 2021
https://www.timesofisrael.com/real-world-israeli-data-shows-south-african-variant-better-at-bypassing-vaccine/

"The South African variant of the coronavirus is notably more adept at 'breaking through' the Pfizer-BioNTech vaccine than other variants are, Israeli scientists have found, in a first-of-its-kind real-world study… A team from Tel Aviv University and the Clalit healthcare organization sequenced the swabs of 150 Israelis who tested positive for COVID-19 despite having been vaccinated. In their study, the prevalence of the South African strain among vaccinated individuals who were infected despite their inoculation was eight times higher than its prevalence in the unvaccinated infected population."

[605] ***BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting***
New England Journal of Medicine
Noa Dagan, Noam Barda, *et al*.
February 24, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2101765

"**Background**: … In this study, data from Israel's largest health care organization were used to evaluate the effectiveness of the BNT162b2 mRNA vaccine…

Results: Each study group included 596,618 persons. Estimated vaccine effectiveness for the study outcomes at days 14 through 20 after the first dose and at 7 or more days after the second dose was as follows: for documented infection, 46% and 92% (95% CI, 88 to 95); for symptomatic Covid-19, 57% (95% CI, 50 to 63) and 94% (95% CI, 87 to 98); for hospitalization, 74% (95% CI, 56 to 86) and 87% (95% CI, 55 to 100); and for severe disease, 62% (95% CI, 39 to 80) and 92% (95% CI, 75 to 100), respectively. Estimated effectiveness in preventing death from Covid-19 was 72% (95% CI, 19 to 100) for days 14 through 20 after the first dose."

VAERS and other Adverse-Event Reporting Systems

About VAERS

[606] ***About VAERS (Vaccine Adverse Event Reporting System)***
Department of Health and Human Services (HHS)
https://vaers.hhs.gov/about.html

> "Established in 1990, the Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA)."

[607] ***Report an Adverse Event to VAERS***
Department of Health and Human Services (HHS)
https://vaers.hhs.gov/reportevent.html

> "Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) **punishable by fine and imprisonment** [*emphasis added*]."

[608] **18 U.S. Code § 1001 - Statements or entries generally**
https://www.law.cornell.edu/uscode/text/18/1001

> "(a)Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—
>
> (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
>
> (2) makes any materially false, fictitious, or fraudulent statement or representation; or
>
> (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;
> shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both. If the matter relates to an offense under chapter 109A, 109B, 110, or 117, or section 1591, then the term of imprisonment imposed under this section shall be not more than 8 years."

VAERS and the Underreporting of Adverse Events

[609] ***Guide to Interpreting VAERS Data***
Department of Health and Human Services (HHS)
https://vaers.hhs.gov/data/dataguide.html

> "VAERS is a passive reporting system, meaning that reports about adverse events are not automatically collected, but require a report to be filed to VAERS… 'Underreporting' is one of the main limitations of passive surveillance systems, including VAERS. The term, underreporting refers to **the fact that VAERS receives reports for only a small fraction of actual adverse events** [*emphasis added*]."

Note: The citations below are presented in reverse, chronological order.

[610] **Video and transcript: Interview with Eileen Iorio, Stan Gotshall, and Wayne Rhode**
Children's Health Defense
August 17, 2021
Provides an overview of some of the known problems with the VAERS system, including indications of under-reporting of adverse events, such as the 'Lazarus Report' by Harvard Pilgrim Health Care.
https://childrenshealthdefense.org/transcripts/the-defender-show-vaccine-safety-advocate-tells-rfk-jr-vaers-protects-vaccine-makers-not-kids/

[611] ***Electronic Support for Public Health–Vaccine Adverse vent Reporting System (ESP:VAERS)***
Harvard Pilgrim Health Care, Inc.
Ross Lazarus
September 30, 2010
https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

> "**Scope**: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs…
>
> **Results**: … Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, **fewer than 1% of vaccine adverse events are reported**. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed [*emphasis added*]. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.
>
> Unfortunately, there was never an opportunity to perform system performance assessments

because the necessary CDC contacts were no longer available and the **CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation** [*emphasis added*]."

[612] ***The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices***
Committee on Government Reform (US)
October 12, 2000
https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

"**Childhood Vaccine Studies**: The Act called for the Institute of Medicine [IOM] to review existing studies and medical literature and provide a foundation for recommendations on vaccine injury causation. In reports issued in 1991 and 1994, IOM published several conclusions regarding the scarcity of knowledge about vaccine safety, citing severe limits in data and research capability. Of the 76 adverse events IOM reviewed for a causal relationship, 50 (66 percent) had no or inadequate research.

Specifically, IOM Committees identified the following limitations of existing knowledge: 1) Inadequate understanding of biologic mechanisms underlying adverse events; 2) Insufficient or inconsistent information from case reports and case series; 3) Inadequate size or length of follow-up of many population-based epidemiological studies; 4) Limitations of existing surveillance systems to provide persuasive evidence of causation, and 5) Few published epidemiological studies.

IOM warned that 'if research capacity and accomplishments [are] not improved, future reviews of vaccine safety [will be] similarly handicapped.' IOM recommends: 'More research could be done on potential long-term adverse effects from vaccines as well as the potential of vaccines to induce or worsen immune disorders.' CDC agrees that there remains 'uncertainty about estimates of the risk associated with vaccination' and that to 'continue research to improve the understanding of vaccine risks is critical.'…

Vaccine Adverse Events Reporting System: … While the Vaccine Adverse Events Reporting System [VAERS] may be lauded as the "front line" of vaccine safety, the lack of enforcement provisions and effective monitoring of reporting practices preclude accurate assessments of the extent to which adverse events are actually reported. Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only **a fraction of the serious adverse events** [*emphasis added*].

The quality of VAERS data has been questioned. Because reports are submitted from a variety of sources, some inexperienced in completing data forms for medical studies, many reports omit important data and contain obvious errors. Assessment is further complicated by the administration of multiple vaccines at the same time, following currently recommended vaccine schedules, because there may be no conclusive way to determine which vaccine or combination of vaccines caused the specific adverse event."

VAERS and COVID-19 Vaccinations

[613] **#OpenVAERS**
https://www.openvaers.com/

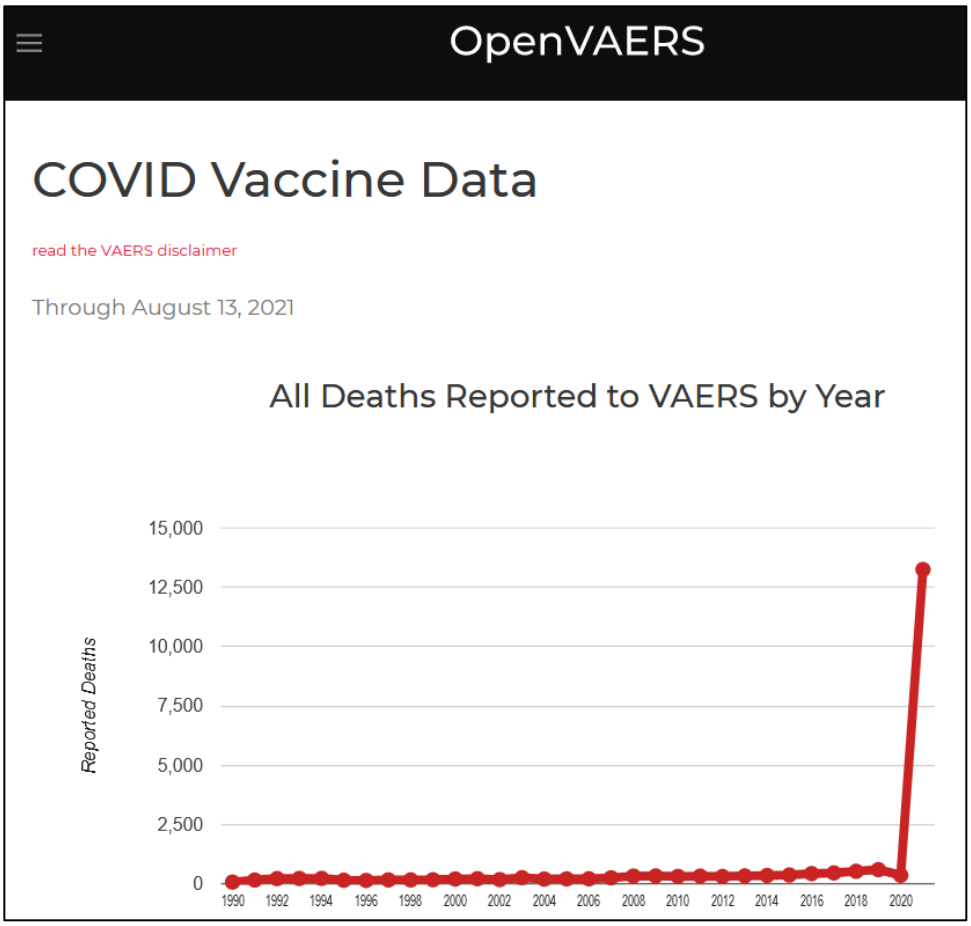
"VAERS is the Vaccine Adverse Event Reporting System put in place in 1990. It is a voluntary reporting system that has been estimated to account for only 1% (read more about underreporting in VAERS) of vaccine injuries. OpenVAERS is built from the HHS data available for download at vaers.hhs.gov.

The OpenVAERS Project allows browsing and searching of the reports without the need to compose an advanced search (more advanced searches can be done at medalerts.org or vaers.hhs.gov)."

Through March 24, 2023:

- 34,965 COVID Vaccine Reported Deaths
- 195,415 Total COVID Vaccine Reported Hospitalizationss
- 1,538,486 COVID Vaccine Adverse Event Reports

[614] ***All Deaths Reported to VAERS by Year***
OpenVAERS
https://www.openvaers.com/covid-data/mortality



[615] ***Urgent Open Letter to the EMA, MHRA, FDA, and CDC***
Doctors for COVID Ethics
July 21, 2021
https://www.globalresearch.ca/jaccuse-governments-worldwide-are-lying-to-you-the-people-to-the-populations-they-purportedly-serve/5750650
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

> "1. Official sources, namely EudraVigilance (EU, EEA, Switzerland), MHRA (UK) and VAERS (USA), have now recorded **more Injuries and Deaths from the 'Covid' vaccine roll-out than from all previous vaccines combined** since records began [*emphasis added*]…
>
> 2. The Signal of Harm is now indisputably overwhelming, and, in line with universally accepted ethical standards for clinical trials, Doctors for Covid Ethics demands that the 'Covid' vaccine programme be halted immediately."

[616] ***The epidemiology of fatalities reported to the Vaccine Adverse Event Reporting System 1990–1997***
Pharmacoepidemiology & Drug Safety
Linda E. Silvers, Susan S. Ellenberg, *et al*.
October 25, 2001
https://pubmed.ncbi.nlm.nih.gov/11760487/

> "**Results**: A total of 1266 fatalities were reported to VAERS during July 1990 through June 1997."

[617] ***Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997–2013***
Clinical Infectious Diseases
Pedro L. Moro, Jorge Arana, *et al*.
May 28, 2015
https://academic.oup.com/cid/article/61/6/980/451431

> From 'Table 1. Death Reports in the Vaccine Adverse Event Reporting System Among Persons Vaccinated 1 July 1997–31 December 2013':
>
> **Total reports**: 2149

Note: The citations below are presented in reverse, chronological order.

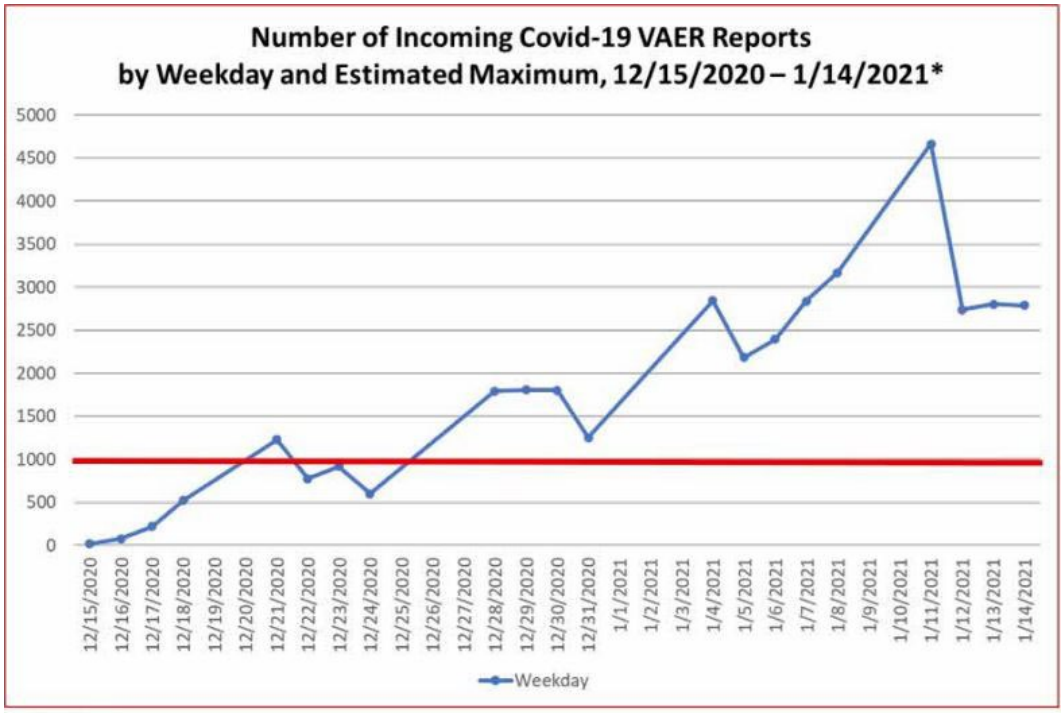
[618] **ADDED since 2/8/2022**
The Banality of VAERS
Josh Guetzkow, senior lecturer at Hebrew University of Jerusalem
March 21, 2023
https://jackanapes.substack.com/p/the-banality-of-vaers
PDF of FOIA documents: General Dynamics monthly reports
https://jackanapes.substack.com/api/v1/file/c0ef992e-ecb5-40dd-a0f5-752e35775f4d.pdf

> "In December I wrote about some FOIA'd contracts between the CDC and private contractors it hired to process the anticipated deluge of COVID-19 VAERS reports. Recall they were expecting **an increase from 1,000 reports a week to 1,000 reports a day**, and even that turned out to be a colossal underestimate.
>
> Just how colossal? The same anonymous source who obtained those contracts sent me FOIA'd reports from the main contractor, General Dynamics Information Technology (GDIT), to the CDC's immunization safety office. General Dynamics is a major defense contractor, and these monthly reports read like a casualty report from a battlefield or a way to keep track of the body count... They are cataloguing a mass casualty event and the significance of the deluge of reports is reduced to a question of billable hours, adequate server space, and how to streamline the processing of this massive catalogue of human suffering…
>
> Below I've pasted screenshots of some of the key bits, with my highlighting and brief commentary/summary…"

Content from January 2021 report (pp. 8-9 of PDF of FOIA documents linked above):

1 *Overview*

This document will provide an overview of GDIT's activities related to the VAERS SAR-CoV-2 response. Two vaccines have been released since the last report. Since release the number of incoming COVID-19 reports has significantly exceeded the estimated maximum of 1,000 reports per day (per the chart below). As a result, GDIT is unable to meet processing and other timeframes (data processing, telephone inquiries, clinical inquries, etc.). GDIT has reache out to the Pogram office and OAS for guidance and support.



*Red line = estimated "worst case" scenario of 1,000 reports per day

December Covid reports have also resulted in record metrics in multiple categories including:

- Number of incoming reports: 19,046
- Number of Web reports received: 11,266
- Number of website visits: 343,964
- Number of inquiries: 2,683
- Number of medical records requested: 2,526

Content from April 2021 report (pp. 17-18 of PDF of FOIA documents linked above):

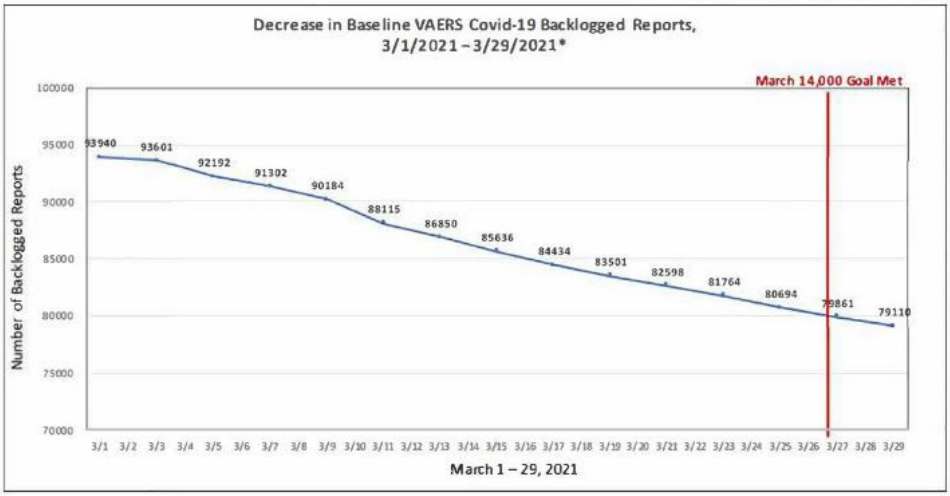
During the reporting period, VAERS continued to be impacted by the surge in Covid-19 related reports, as evidenced by the following metrics:

- Number of incoming reports: 98,687 (increase from February 2021)
- Number of website visits: 1,963,535 (increase from February 2021)
- Number of datasets downloaded: 169,783 (increase from February 2021)
- Number of inquiries from the public: 28,472 (increase from February 2021).

While staff processed over 60,200 reports in March, a record high, they were unable to keep up with the increased surge in reports. Additonal surge hiring began with the receipt of additional funding.

1. **Processing of Backlog Reports** A contract modification, to provide for backlog remediation, was issued in March. During the reporting period, GDIT filled over 90 backlog staffing positions and began processing the backlogged reports. We exceeded the March 14,000 processing goal by over 2,000 reports.

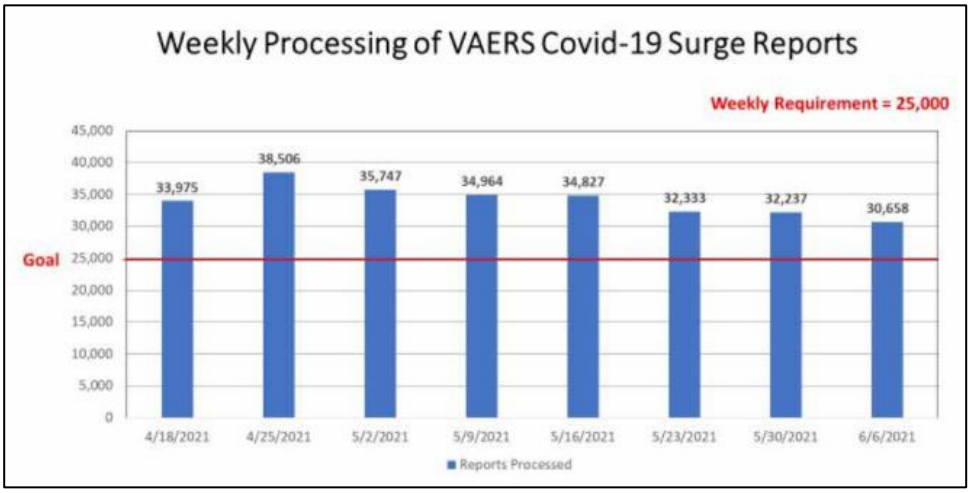
*Total number of processed reports = 15,216
14,000+ reports to be processed in March 2021.



2. **Processing of Incoming Surge Reports**

GDIT also began hiring staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). Over 200 staff have been hired and are in training. **GDIT will begin processing 25,000 reports per week during the week of April 19th.**

Content from June 2021 report (p. 25 of PDF of FOIA documents linked above):



[619] **ADDED since 2/8/2022**

CDC Finally Released Its VAERS Safety Monitoring Analyses for COVID Vaccines via FOIA
Josh Guetzkow, senior lecturer at Hebrew University of Jerusalem
January 4, 2023
https://jackanapes.substack.com/p/cdc-finally-released-its-vaers-safety

"**Summary**:

- CDC's VAERS safety signal analysis based on reports from Dec. 14, 2020 – July 29, 2022 for mRNA COVID-19 vaccines shows **clear safety signals for death and a range of highly concerning thrombo-embolic, cardiac, neurological, hemorrhagic, hematological, immune-system and menstrual adverse events** (AEs) among U.S. adults.
- There were 770 different types of adverse events that showed safety signals in ages 18+, of which over 500 (or 2/3) had a larger safety signal than myocarditis/pericarditis.
- The CDC analysis shows that the number of serious adverse events reported in less than two years for mRNA COVID-19 vaccines is 5.5 times larger than all serious reports for vaccines given to adults in the US since 2009 (~73,000 vs. ~13,000)…
- There are 96 safety signals for 12-17 year-olds, which include: myocarditis, pericarditis, Bell's Palsy, genital ulcerations, high blood pressure and heartrate, menstrual irregularities, cardiac valve incompetencies, pulmonary embolism, cardiac arrhythmias, thromboses, pericardial and pleural effusion, appendicitis and perforated appendix, immune thrombocytopenia, chest pain, increased troponin levels, being in intensive care, and having anticoagulant therapy.
- There are 66 safety signals for 5-11 year-olds, which include: myocarditis, pericarditis, ventricular dysfunction and cardiac valve incompetencies, pericardial and pleural effusion, chest pain, appendicitis & appendectomies, Kawasaki's disease, menstrual irregularities, vitiligo, and vaccine breakthrough infection."

[620] **ADDED since 2/8/2022**

Delayed Vigilance: A Comment on Myocarditis in Association with the COVID-19 Injections
International Journal of Vaccine Theory, Practice, and Research — Children's Health Defense
Karl Jablonowski and Brian S. Hooker
October 17, 2022
https://ijvtpr.com/index.php/IJVTPR/article/view/61

"**Abstract**: This comment documents the fact that the CDC delayed reporting the incidence of myocarditis to the general public for **three months** after the first statistically significant signal appeared in the VAERS database. The delay kept about 120,000,000 Americans in the dark until after they had already unknowingly exposed themselves to one or more doses of the COVID-19 injections that were, according to the analysis presented here, in all probability, the proximate cause of the increased incidence of myocarditis, especially in young male Americans from 8 to 21 years of age."

[621] **ADDED since 2/8/2022**

CDC Admits It Never Monitored VAERS for COVID Vaccine Safety Signals

The Defender
Josh Guetzkow
June 21, 2022
https://childrenshealthdefense.org/defender/cdc-vaers-covid-vaccine-safety/

> "In a stunning development, the Centers for Disease Control and Prevention (CDC) last week admitted — despite assurances to the contrary — the agency **never analyzed** the Vaccine Adverse Event Reporting System (VAERS) for safety signals for COVID-19 vaccines.
>
> The admission was revealed in response to a Freedom of Information Act (FOIA) request submitted by Children's Health Defense (CHD)…
>
> CDC officials stated publicly that 'COVID-19 vaccine safety monitoring is the most robust in U.S. history,' …
>
> The lynchpin of [*the CDC's*] safety monitoring was to mine VAERS data for safety signals by calculating what are known as proportional reporting ratios (PRRs).
>
> This is a method of comparing the proportion of different types of adverse events reported for a new vaccine to the proportion of those events reported for an older, established vaccine.
>
> If the new vaccine shows a significantly higher reporting rate of a particular adverse event relative to the old one, it counts as a safety signal that should then trigger a more thorough investigation.
>
> The briefing document states, '**CDC will perform PRR data mining on a weekly basis or as needed**.' …
>
> ***Note**: The briefing document also states "FDA will perform data mining at least biweekly (with stratified data mining monthly) using empirical Bayesian data mining to identify AEs reported more frequently than expected following vaccination with COVID-19 vaccines."*
>
> And yet, in the agency's response to the FOIA request, it wrote that '**no PRRs were conducted by CDC**. Furthermore, **data mining is outside of the agency's purview**.'"

[622] **ADDED since 2/8/2022**

Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19

Centers for Disease Control and Prevention (CDC)
January 29, 2022
https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

> See also 0.
>
> "**Executive Summary**: CDC and FDA will perform routine VAERS surveillance to identify potential new safety concerns for COVID-19 vaccines. This surveillance will include generating tables summarizing automated data from fields on the VAERS form for persons who received COVID-19 vaccines (e.g., age of vaccinee, COVID-19 vaccine type, adverse event). Enhanced surveillance (i.e., automated data and clinical review) will be implemented after reports of the following adverse events of special interest (AESIs): death, COVID19

disease, Guillain-Barre Syndrome (GBS), seizure, stroke, narcolepsy/cataplexy, anaphylaxis, vaccination during pregnancy, acute myocardial infarction, myopericarditis, coagulopathy (including thrombocytopenia, disseminated intravascular coagulopathy [DIC], and deep venous thrombosis [DVT]), Kawasaki's disease, multisystemic inflammatory syndrome in children (MIS-C), multisystemic inflammatory syndrome in adults (MIS-A), transverse myelitis, Bells Palsy, and appendicitis. Abstraction of medical records associated with reports of these conditions will be performed using an internal CDC website (i.e., behind CDC's firewall). Data entered into the abstraction website will be stored on CDC servers and used to populate data tables, from which automated reports will be generated and analyzed on a periodic basis. Enhanced surveillance (i.e., automated data and clinical review) will also be implemented after reports of pregnancy complications, stillbirths, congenital anomalies, and vaccination errors…

2.3.1 Proportional Reporting Ratio (PRR): CDC will perform PRR data mining on a weekly basis or as needed. PRRs compare the proportion of a specific AE following a specific vaccine versus the proportion of the same AE following receipt of another vaccine (see equation below Table 4). A safety signal is defined as a PRR of at least 2, chi-squared statistic of at least 4, and 3 or more cases of the AE following receipt of the specific vaccine of interest…

2.3.2 Data mining: FDA will perform data mining at least biweekly (with stratified data mining monthly) using empirical Bayesian data mining to identify AEs reported more frequently than expected following vaccination with COVID-19 vaccines, using published criteria [12, 14]. Vaccine product-specific AE pairs following specific COVID-19 vaccines with reporting proportions at least twice that of other vaccines in the VAERS database (i.e., lower bound of the 90% confidence interval of the Empirical Bayesian Geometric Mean [EB05] >2) will be evaluated. Data mining runs can be adjusted and/or stratified by possible confounding variables such as age, sex, season of administration, and type of vaccines. FDA and CDC will share and discuss results of data mining analyses and signals."

[623] ***Who wants to be a Millionaire?***
Steve Kirsch, Executive Director of the Vaccine Safety Research Foundation
November 22, 2021
https://stevekirsch.substack.com/p/who-wants-to-be-a-millionaire

"Some people have questioned me about my million dollar offers. Yes, they are TOTALLY serious. There are no tricks. The only trick is I only bet on things where I know I can't lose the offer…

Here is a list of my million dollar offers. They are all done to expose corruption or to show people that nobody can dispute our calculations, even with a very large incentive...

$1M research grant if you think Mathew Crawford made a math error that would change the result.

I'm offering a $1M research grant to the first researcher to publish a paper that disproves Mathew Crawford's analysis of the death data that shows that the vaccines have killed over 150,000 people in the US."

Term sheet: https://www.skirsch.com/covid/Grant.pdf

Crawford's analysis, *Estimating Vaccine-Induced Mortality*:

- Part I: https://roundingtheearth.substack.com/p/estimating-vaccine-induced-mortality
- Part II: https://roundingtheearth.substack.com/p/estimating-vaccine-induced-mortality-e07

[624] ***New VAERS analysis reveals hundreds of serious adverse events that the CDC and FDA never told us about***
Steve Kirsch and Albert Benavides
November 9, 2021
https://stevekirsch.substack.com/p/new-vaers-analysis-reveals-hundreds
Team of Vaccine Safety Experts: https://stevekirsch.substack.com/p/my-team-of-vaccine-safety-experts

> "In a brand new VAERS data analysis …, we found hundreds of serious adverse events that were completely missed by the CDC that should have been mentioned in the informed consent document that are given to patients. And we found over 200 symptoms that occur at a higher relative rate than myocarditis (relative to all previous vaccines over the last 5 years). All together, there were over 4,000 VAERS adverse event codes that were elevated by these vaccines by a factor of 10 or more over baseline that the CDC should have warned people about…
>
> Here's what the evidence shows:
>
> 1. The COVID vaccines are the most dangerous vaccines in human history. They are 800 times more deadly than the smallpox vaccine which was the previous record holder. The vaccines have killed over 150,000 Americans and permanently disabled even more…
>
> 5. The serious events we highlight below are all consistent with the mechanism of action that Robert Malone and I first described in the Darkhorse podcast. Namely, that **the spike protein** that is produced in response to the delivery of the mRNA **is cytotoxic and results in blood clots, inflammation and scarring throughout your body** [emphasis added] which then **creates a wider range of severe adverse events than any vaccine in human history**…
>
> 9. The serious events are primarily centered around menstruation, blood clots, inflammation and scarring, cardiovascular damage, and neurological damage, just as we predicted in the podcast in June of 2021.
>
> 10. There are hundreds of serious adverse events that are caused by these vaccines. This of course is shocking to people since the CDC has repeatedly said you can't ascribe causality to data in VAERS. Not true. The VAERS data analysis (temporal data, the dose dependency, and the elevated reporting rates compared to baseline) provide ample signal to enable us to show causality on all of these events using the five Bradford-Hill criteria applicable to vaccines…
>
> 13. It is unlikely that anyone in the world will want to debate us publicly on any of the claims above (or on any of my articles or on any of Mathew's articles), but if you are a prominent supporter of the false narrative and want a public debate, we are here for you. Our team would be thrilled to accept the challenge as we have no desire to spread misinformation. If we got it wrong, we are happy to correct our mistakes if you can explain to us clearly the mistake

we made and the correction you suggest (e.g., the "right" answer). Yet even with multiple million dollar incentives (listed in this article), nobody seems to be interested in showing how we got it wrong. Everyone talks about how bad the vaccine misinformation problem is, but nobody is willing to do anything to show that we got it wrong…

What we found in the VAERS analysis below can be verified by anyone because it is all publicly accessible…

You can easily verify any entry yourself via manual queries to any VAERS interface (my favorite is MedAlerts, but others such as openvaers and the HHS site give the same results)."

[625] ***COVID vaccination and age-stratified all-cause mortality risk***
Columbia University
Spiro Pantazatos and Herve Seligmann
October 2021
https://www.researchgate.net/publication/355581860_COVID_vaccination_and_age-stratified_all-cause_mortality_risk

"**Abstract**: Accurate estimates of COVID vaccine-induced severe adverse event and death rates are critical for risk-benefit ratio analyses of vaccination and boosters against SARS-CoV-2 coronavirus in different age groups. However, existing surveillance studies are not designed to reliably estimate life-threatening event or vaccine-induced fatality rates (VFR). Here, regional variation in vaccination rates was used to predict all-cause mortality and non-COVID deaths in subsequent time periods using two independent, publicly available datasets from the US and Europe (month- and week-level resolutions, respectively). Vaccination correlated negatively with mortality 6-20 weeks post-injection, while vaccination predicted all-cause mortality 0-5 weeks post-injection in almost all age groups and with an age-related temporal pattern consistent with the US vaccine rollout. Results from fitted regression slopes ($p<0.05$ FDR corrected) suggest a US national average VFR of 0.04% and higher VFR with age (VFR=0.004% in ages 0-17 increasing to 0.06% in ages >75 years), and **146K to 187K vaccine-associated US deaths between February and August, 2021**. Notably, adult vaccination increased ulterior mortality of unvaccinated young (<18, US; <15, Europe). Comparing our estimate with the CDC-reported VFR (0.002%) suggests **VAERS deaths are underreported by a factor of 20** [*emphasis added*], consistent with known VAERS under-ascertainment bias. Comparing our age-stratified VFRs with published age-stratified coronavirus infection fatality rates (IFR) suggests the risks of COVID vaccines and boosters outweigh the benefits in children, young adults, and older adults with low occupational risk or previous coronavirus exposure. Our findings raise important questions about current COVID mass vaccination strategies and warrant further investigation and review."

[626] ***Estimating the number of COVID vaccine deaths in America***
Jessica Rose and Mathew Crawford
September 2021
https://downloads.regulations.gov/CDC-2021-0089-0024/attachment_1.pdf
Updated November 1, 2021: https://www.skirsch.com/covid/Deaths.pdf

> "**Summary**: Using the VAERS database and independent rates of anaphylaxis events from a Mass General study, we computed a **41X under-reporting factor for serious adverse events** in VAERS, leading to an **estimate of over 150,000 excess deaths caused by the vaccine** [*emphasis added*].
>
> The estimates were validated multiple independent ways.
>
> There is no evidence that these vaccines save more lives than they cost. Pfizer's own study showed that adverse events consistent with the vaccine were greater than the lives saved by the vaccine to yield a net negative benefit. Without an overall statistically significant all-cause mortality benefit, and evidence of an optional medical intervention that has likely killed over 150,000 Americans so far, vaccination mandates are not justifiable and should be opposed by all members of the medical community.
>
> Early treatments using a cocktail of repurposed drugs with proven safety profiles are a safer, more effective alternative which always improves all-cause mortality in the event of infection and there are also safe, simple, and effective protocols for prophylaxis."

[627] ***Safety Signals for COVID Vaccines Are Loud and Clear. Why Is Nobody Listening?***
Children's Health Defense
Josh Guetzkow
September 29, 2021
https://childrenshealthdefense.org/defender/safety-signals-covid-vaccines-full-transparency-cdc-fda/

> "On Aug. 30, the CDC Advisory Committee on Immunization Practices (ACIP) voted to recommend Pfizer/BioNTech's mRNA COVID-19 vaccine for people 16 years and older.
>
> In comments I submitted to the committee along with my collaborators, we provided evidence of large safety signals from VAERS, using published CDC methods to analyze the data.
>
> In this article, I describe the safety signals highlighted in our comments, which raise pressing questions about the CDC's and FDA's COVID vaccine safety monitoring efforts.
>
> To begin with, there has been an unprecedented increase in the number of adverse event reports to VAERS associated with COVID-19 vaccines…
>
> It is hard to imagine how anyone can look at these numbers and not be at least a little bit concerned. Yet many people are dismissive, saying the unprecedented number of reports is due to the unprecedented number of vaccinations being administered.
>
> I crunched the numbers, and even after taking into account the total number of vaccinations, the number of reports for COVID vaccines still towers over previous years…
>
> For each adverse event type, the table [] shows the COVID-to-flu ratio, which simply shows how many more events were reported per million doses of COVID-19 vaccines compared to

the number per million doses of seasonal influenza vaccines…

Table 1 (below) shows a comparison of VAERS reports for COVID-19 vaccines versus flu vaccines per million doses administered for a range of different event types and age groups.

For each adverse event type, the table shows the COVID-to-flu ratio, which simply shows how many more events were reported per million doses of COVID-19 vaccines compared to the number per million doses of seasonal influenza vaccines..

The first thing to notice is that for every type of adverse event for every age group, there were more reports per million doses of COVID-19 vaccines than for flu vaccines. If you look at the bottom row for all age groups (12 and older), you see that for every million vaccine doses administered, there were **19 times more reports to VAERS for COVID-19 vaccines than for flu vaccines, 28 times more serious events, 91 times more deaths**, 3 times more reports of Guillain-Barré syndrome (GBS), 276 times more reports of coagulopathy; 126 times as many reports of myocardial infarction; and 136 times more reports of myopericarditis [*emphasis added*]."

Table 1. COVID-to-Flu Ratio Reporting Ratios per Million Vaccine Doses

Ages	All Reports	Serious Reports	Death	GBS	Coagulopathy	Myocardial Infarction	Myo-pericarditis
12-17	25	34	32	7	74	n.e.	1251
18-49	26	25	64	3	226	403	81
50-64	18	26	85	3	239	121	22
65+	11	30	98	3	370	88	10
Overall	19	28	91	3	276	126	136

Notes: The COVID-to-Flu ratio is the ratio of the COVID-19 reporting rate to the flu reporting rate per million vaccine doses. All differences between COVID-19 and flu reporting rates are statistically significant. Myocardial infarctions for 12-17 year-olds is non-estimable (n.e.) because there were no reports of M.I. for flu vaccines in that age group. GBS is Guillan-Barré Syndrome. Flu reporting rates represent the total reports to VAERS across the 2015/16 to 2019/20 flu seasons for each age group. Covid-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group from Dec. 15, 2020 through Aug. 6, 2021. Vaccine doses estimated using data from the CDC and the US Census Bureau. COVID-19 vaccination totals are from Aug. 5, 2021. All reports with SARS-CoV-2 infection or COVID-19 were excluded from counts. Only reports that originated from U.S. states and D.C. were included.

[628] **Virtual meeting (video): *Vaccines and Related Biological Products Advisory Committee*, *remarks by Dr. Jessica Rose***
Food and Drug Administration (FDA)
September 17, 2021
https://youtu.be/WFph7-6t34M?t=14985

Rose (starting at 4:09:45): "My name is Dr. Jessica Rose, and I'm a viral immunologist and computational biologist. I've taken it upon myself to become a VAERS analyst to organize the data into comprehensive figures to convey information to the public, in both published works and video mediums…

There's an **over 1,000% increase in the total number of adverse events** for 2021, and we are not done with 2021 [*emphasis added*]. This is highly anomalous on both fronts [*events and deaths*]. These increased reporting rates are not due to increased rates in injections and not due to simulated reporting…

The onus is on the public-health officials – the FDA, the CDC and policymakers – to answer

for these anomalies and acknowledge the clear risk signals emerging from VAERS data, and to confront the issue of COVID-injectable products' use risk that, in my opinion, outweigh any potential benefit associated with these products, especially for children."

[629] **Civil Action: *Whistleblower 'Jane Doe' Declaration***
July 13, 2021
https://renzlaw.godaddysites.com/45k-whistleblower-suit

"I am a computer programmer with subject matter expertise in the healthcare data analytics field, an honor that allows me access to Medicare and Medicaid data maintained by the Centers for Medicare and Medicaid Services (CMS). I earned a B.S. degree in Mathematics and have, over the last 25 years, developed over 100 distinct healthcare fraud detection algorithms, both in the public and private sector. It has been my mission to protect federal tax dollars by preventing and detecting healthcare fraud, a process which leads to both recovery of overpayments and law enforcement leads… When the COVID-19 vaccine clearly became associated with patient death and harm, I was naturally inclined to investigate the matter.

It is my professional estimate that VAERS (the Vaccine Adverse Event Reporting System) database, while extremely useful, **is under-reported by a conservative factor of at least 5** [*emphasis added*]. On July 9, 2021, there were 9,048 deaths reported in VAERS. I verified these numbers by collating all of the data from VAERS myself, not relying on a third party to report them. In tandem, I queried data from CMS medical claims with regard to vaccines and patient deaths, and have assessed that the deaths occurring within 3 days of vaccination are higher than those reported in VAERS by a factor of at least 5. This would indicate the true number of vaccine-related deaths was at least 45,000. Put in perspective, the swine flu vaccine was taken off the market which only resulted in 53 deaths.

I declare **under penalty of perjury** under the laws of the United States of America that the foregoing is true and correct [*emphasis added*]."

[630] ***Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database Interim: Results and Analysis***
PAMBAYESIAN Project
Scott Mclachlan, Magda Osman, *et al*.
June 2021
https://www.researchgate.net/publication/352837543_Analysis_of_COVID-19_vaccine_death_reports_from_the_Vaccine_Adverse_Events_Reporting_System_VAERS_Database_Interim_Results_and_Analysis

"**Abstract**: Clinically trained reviewers have undertaken a detailed analysis of a sample of the early deaths reported in VAERS (250 out of the 1644 deaths recorded up to April 2021). The focus is on the extent to which the reports enable us to understand whether the vaccine genuinely caused or contributed to the deaths. Contrary to claims that most of these reports are made by lay-people and are hence clinically unreliable, we identified health service employees as the reporter in at least 67%. The sample contains only people vaccinated early in the programme, and hence is made up primarily of those who are elderly or with significant health conditions. Despite this, there were only 14% of the cases for which a vaccine reaction could be ruled out as a contributing factor in their death…

3. Analysis of the VAERS data for COVID-19 Vaccines: … Figure 4 highlights that **50% died in less than 48 hours after receiving their COVID-19 vaccination**. This increases to 80% when we extend to the first week post-vaccination [*emphasis added*]. A further 10% of deaths occurred in the second week…

Conclusions: [T]he only patients where a vaccine allergic reaction be ruled out as contributing to death were 34 (14%) who were all either already bedridden, at end of life, and expected to die anyway from a serious comorbid like lung cancer or were on palliative hospice care."

[631] ***A Report on the U.S. Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals***
Science, Public Health Policy, and The Law
Jessica Rose
May 2021
https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_a0a813acbfdc4534a8cb50cf85193d49.pdf

"**Abstract**: Following the global roll-out and administration of the Pfizer/BioNTech (BNT1 62b2) and Moderna (mRNA-1 273) COVID-1 9 vaccines1 on December 17, 2020 in the United States, and of the Janssen COVID-19 Vaccine PF (produced by Johnson & Johnson) on April 1st, 2021, tens of thousands of individuals have reported adverse events (AEs) using the Vaccine Adverse Events Reports System (VAERS). This work summarizes this data to date and serves as information for the public and a reminder of the relevance of any adverse events, including deaths that occur as a direct result of biologicals as prophylactic treatments. This is especially relevant in the context of technologically novel treatments in the experimental phase of development. Analysis suggests that the vaccines are likely the cause of reported deaths, spontaneous abortions, anaphylactic reactions and cardiovascular, neurological and immunological AEs…

Conclusion: … [D]ue to both the problems of under-reporting and the lag in report processing, this analysis reveals a strong signal from the VAERS data that the risk of suffering an SAE [*Severe Adverse Event*] following injection is significant and that the overall risk signal is high."

Other Adverse-Event Reporting Systems and Related Issues

[632] **ADDED since 2/8/2022**

V-safe

Centers for Disease Control and Prevention (CDC)

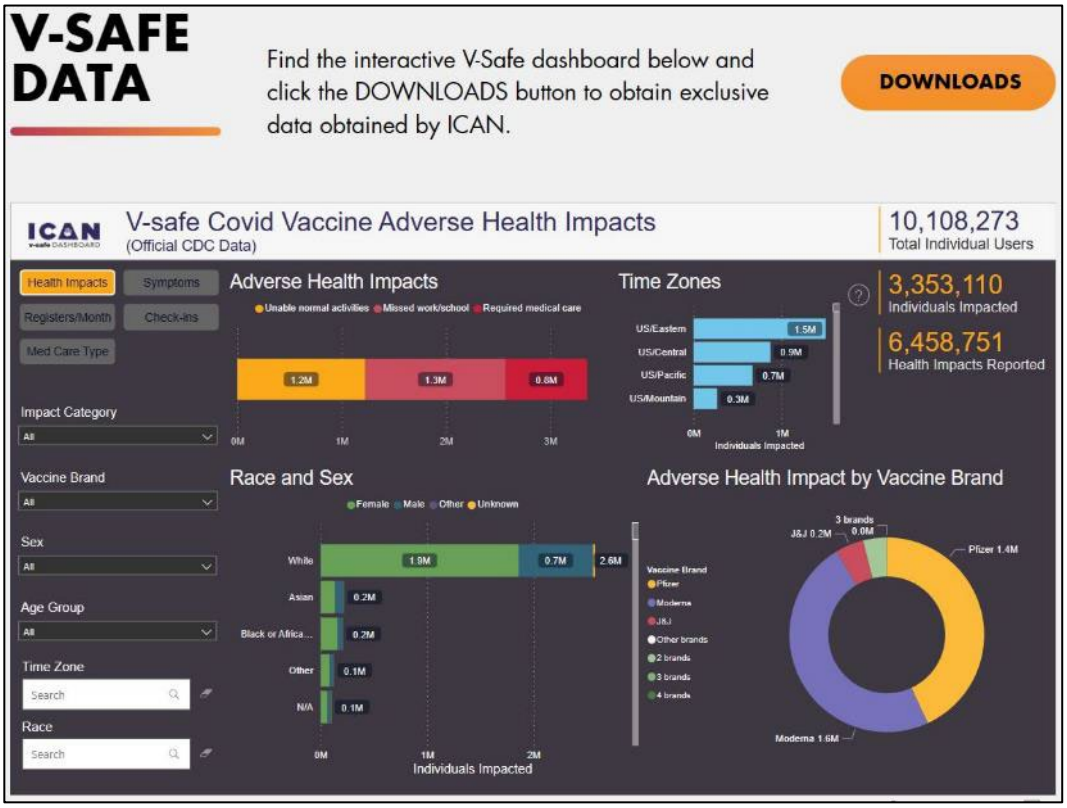
October 18, 2022

https://icandecide.org/article/v-safe/

"The CDC created v-safe, a smartphone-based program, to collect health assessments after Covid-19 vaccination. Approximately 10 million people signed-up and submitted health reports after Covid-19 vaccination.

ICAN's legal team sued the CDC twice leading to a court order requiring release of the data. ICAN has taken the CDC's official raw data and created a dashboard interface which allows users to graphically view the 144+ million health entries obtained by ICAN."

Of 10,108,273 individual users, roughly 800,000 or **7.9%** experienced adverse events following COVID-19 vaccination that "required medical care."



[633] **UPDATED since 2/8/2022**
#VigiAccess
http://vigiaccess.org/

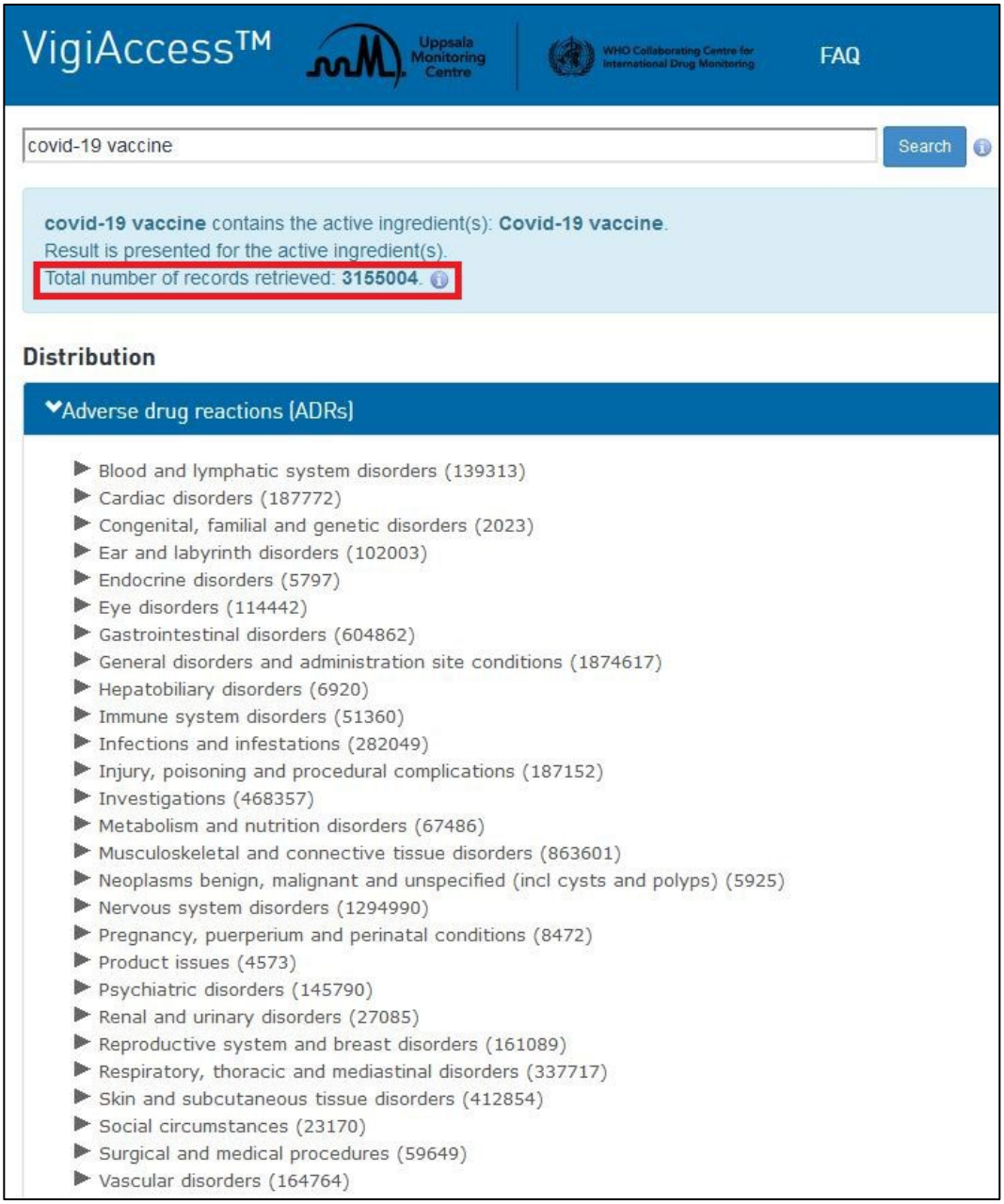
"VigiAccess was launched by the World Health Organization (WHO) in 2015 to provide public access to information in VigiBase, the WHO global database of reported potential side effects of medicinal products. Side effects – known technically as adverse drug reactions (ADRs) and adverse events following immunization (AEFIs) – are reported by national pharmacovigilance centres or national drug regulatory authorities that are members of the WHO Programme for International Drug Monitoring (PIDM). WHO PIDM was created in 1968 to ensure the safer and more effective use of medicinal products…

Special note regarding COVID-19 vaccine data: To see VigiBase data on COVID-19 vaccines, **search for "covid-19 vaccine"** [*emphasis added*]. Please note that VigiAccess, as a result of the terminology used to structure the information, will group the data for vaccines by disease (for example, "Measles vaccine", "Mumps vaccine"). This means that even searches for exact tradenames, such as "Comirnaty" or "Covishield", will result in the total number of cases reported for all COVID-19 vaccines. It is not possible in VigiAccess to separate the numbers for specific vaccines.

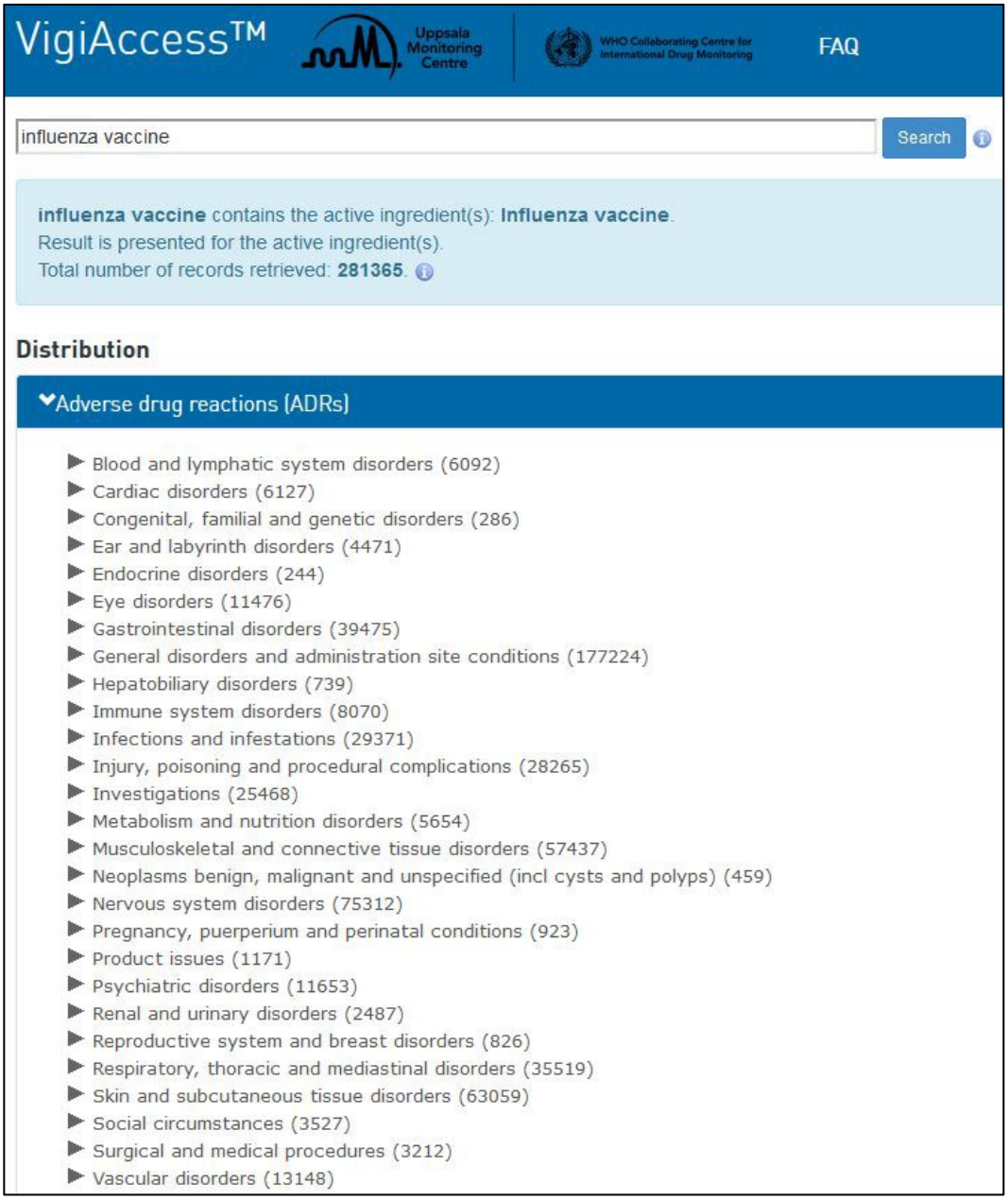
Notes:

- On February 6, 2022, a query of VigiAccess for 'covid-19 vaccine' (as explained above) produced the results below. The 'Total number of records retrieved' was **3,155,004**, and the total for each type of adverse event is presented in parentheses. For comparison, the results of a query for 'influenza vaccine' are also provided, which show 281,365 'Total number of records retrieved' for the years 1968-2022.
- On April 5, 2023, a query of VigiAccess for 'covid-19 vaccine' returned **4,962,301 reports**.

Results of a VigiAccess query for 'covid-19 vaccine'



Results of a VigiAccess query for 'influenza vaccine' (1968-2022)



[634] **UPDATED since 2/8/2022**
#The Yellow Card scheme: *Coronavirus (COVID-19) vaccines adverse reactions: A weekly report covering adverse reactions to approved COVID-19 vaccines*
Medicines and Healthcare products Regulatory Agency (MHRA - UK)
https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions
Coronavirus Vaccines – summary of Yellow Card reporting
Data included: December 9, 2020 to April 20, 2022
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1052493/Coronavirus_vaccine_-_summary_of_Yellow_Card_reporting_25.01.2022.pdf

> "**Summary**: … As of 20 April 2022, for the UK, 169,660 Yellow Cards have been reported for the COVID-19 Pfizer/BioNTech Vaccine, 244,908 have been reported for the COVID-19 Vaccine AstraZeneca, 37,478 for the COVID-19 Vaccine Moderna and 1,634 have been reported where the brand of the vaccine was not specified.
>
> For the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna the overall reporting rate is around 2 to 5 Yellow Cards per 1,000 doses administered."

[635] **EudraVigilance**
European Medicines Agency (EMA)
https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance
Reports on Moderna: https://tinyurl.com/2rj68cr9
Reports on Pfizer: https://tinyurl.com/3jwcnurv
Reports on Astrazeneca: https://tinyurl.com/awws49v6

> **About**: "EudraVigilance is the European data processing network and management system for reporting and evaluation of suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network."

[636] **Video (9m): 2019 Global Vaccine Safety Summit**
World Health Organization
December 2-3, 2019
https://www.bitchute.com/video/hGodcJHccnhh/
"**Purpose of the event**: … the Global Vaccine Safety Summit will be an opportunity to take stock of GACVS accomplishments and look towards priorities for the next decade.
Attendees: The Summit is meant for vaccine safety stakeholders from around the world, including current and former members of the Global Advisory Committee on Vaccine Safety (GACVS), immunisation programme managers, national regulatory authorities, pharmacovigilance staff from all WHO regions, and representatives of UN agencies, academic institutions, umbrella organizations of pharmaceutical companies, technical partners, industry representatives and funding agencies."
https://www.who.int/news-room/events/detail/2019/12/02/default-calendar/global-vaccine-safety-summit

Dr. Heidi Larson, Director of The Vaccine Confidence Project: "There's a lot of safety science that's needed, and without the good science, we can't have good communication… So we need much more investment in safety science…"

Dr. Soumya Swaminathan, Chief Scientist, WHO: "I think we cannot overemphasize the fact that we really don't have very good safety monitoring systems in many countries, and this adds to the miscommunication and misapprehensions because we're not able to give clear-cut answers when people ask questions about the deaths that have occurred due to a particular vaccine..."

Dr. Bassey Okposen, Program Manager, National Emergency Routine Immunization Coordination Centre (NERICC), Abuja, Nigeria: "I cast back my mind to our situation in Nigeria, where at six weeks, ten weeks, fourteen weeks, a child is being given different antigens from different companies, and these vaccines have different adjuvants, different preservatives, and so on… Something crosses my mind – is there a possibility of these adjuvants, preservatives cross-reacting amongst themselves? Has there ever been a study on the possibilities of cross-reactions [*inaudible*] that you can share the experience with us? ..."

Dr. Robert Chen, MD, Scientific Director, Brighton Collaboration (response to Okposen): "Now the only way to tease that out is if you have a large population database, like the vaccine safety data link, as well as some of the other national databases, that are coming to being worthy. Actual vaccine exposure is trapped down to that level of specificity of who is the manufacturer? What is the lot number? Uh, etcetera, etcetera. And there's initiative to try to make the vaccine label information barcoded, so that it includes that level of information, so that in the future, when we do these type of studies we're able to tease that out. And in order to, each time you subdivide, then the sample size gets more and more challenging. And that's what I said earlier today, about that we're really only in the beginning of the era of large data sets where, hopefully, you can start to kind of harmonize the databases from multiple studies. And there is actually an initiative underway … to try to get more national vaccine safety databases linked together so we can start to answer these types of questions that you just raised…"

Larson: "The other thing that's a trend and an issue is not just confidence in providers, but confidence of health-care providers. We have a very wobbly health professional frontline that is starting to question vaccines and the safety of vaccines… When the frontline professionals are starting to question, or they don't feel like they have enough confidence about the safety to stand up to it to the person asking them the questions. I mean most medical-school curriculums, even nursing curriculums, I mean, **in medical school, you're lucky if you have a half day on vaccines**, nevermind keeping up to date with all this [*emphasis added*]."

Systemic and Virological Concerns with COVID-19 Vaccinations

SARS-CoV-2 Spike Protein

[637] ***Understanding mRNA COVID-19 Vaccines***
Centers for Disease Control and Prevention
Updated January 4, 2022
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html

"**How mRNA Vaccines Work** …

First, COVID-19 mRNA vaccines are given in the upper arm muscle. The mRNA will enter the muscle cells and instruct the cells' machinery to produce a **harmless piece** of what is called the spike protein [*emphasis added*]. The spike protein is found on the surface of the virus that causes COVID-19."
Note: For evidence contradicting the claim that the spike protein is 'harmless,' see below.

[638] **ADDED since 2/8/2020**
Letter to U.S. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee in response to "Request for Comments related to consideration of vaccines against SARS-CoV-2"
Patrick Whelan MD PhD, UCLA Pediatric Rheumatology
December 8, 2020
https://childrenshealthdefense.org/wp-content/uploads/Whelan-FDA-letter-re-EAU-Pfizer-.pdf

"Dear Colleagues,

I am a pediatric specialist caring for children with the multisystem inflammatory syndrome (MIS-C). I am concerned about the possibility that the new vaccines aimed at creating immunity against the SARS-CoV-2 spike protein (including the mRNA vaccines of Moderna and Pfizer) have the potential to cause microvascular injury to the brain, heart, liver, and kidneys in a way that is not currently being assessed in safety trials of these potential drugs…

While there are pieces to this puzzle that have yet to be worked out, it appears that the **viral spike protein** that is the target of the major SARS-CoV-2 vaccines **is also one of the key agents causing the damage to distant organs that may include the brain, heart, lung, and kidney**. Before any of these vaccines are approved for widespread use in humans, it is important to assess in vaccinated subjects the effects of vaccination on the heart (perhaps using cardiac MRI, as Puntmann et al. did). Vaccinated patients could also be tested for distant tissue damage in deltoid area skin biopsies, as employed by Magro et al. As important as it is to quickly arrest the spread of the virus by immunizing the population, it would be vastly worse if hundreds of millions of people were to suffer **long-lasting** or even **permanent damage to their brain or heart microvasculature** as a result of failing to appreciate in the short-term an unintended effect of **full-length spike protein-based vaccines** on these other organs."

[639] **ADDED since 2/8/2020**

CDC REMOVES Their Claim That mRNA & Spike Protein "Do Not Last Long In The Body"

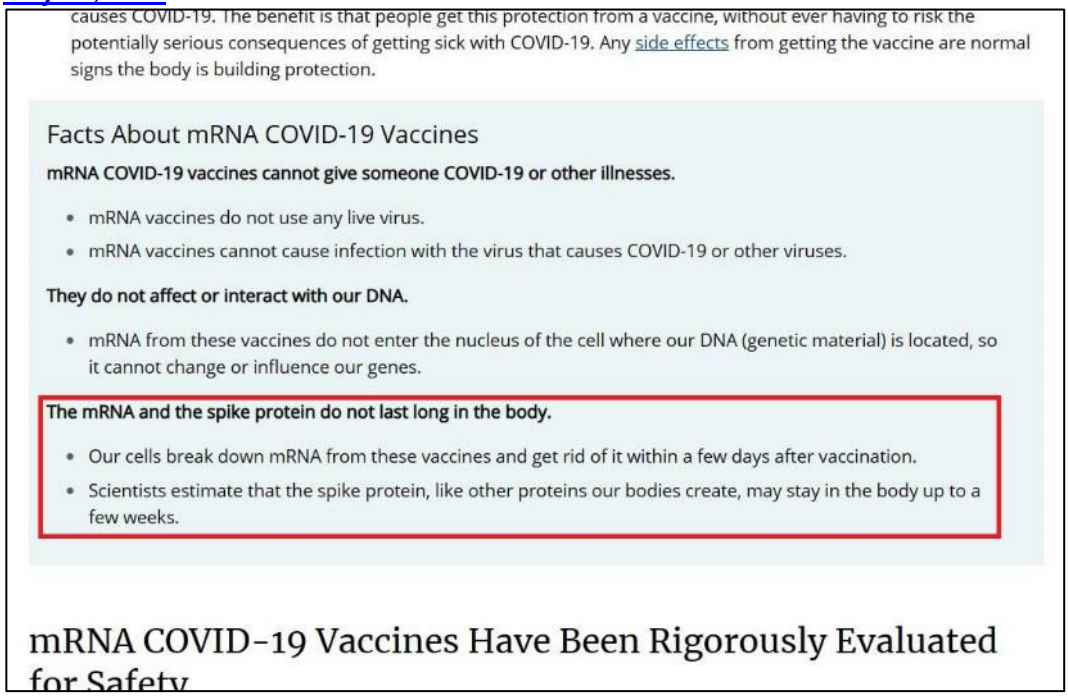
Tim Truth

August 13, 2022

https://timtruth.substack.com/p/cdc-removes-their-claim-that-mrna

CDC Web page: *Understanding mRNA COVID-19 Vaccines*

July 22, 2022



causes COVID-19. The benefit is that people get this protection from a vaccine, without ever having to risk the potentially serious consequences of getting sick with COVID-19. Any side effects from getting the vaccine are normal signs the body is building protection.

Facts About mRNA COVID-19 Vaccines

mRNA COVID-19 vaccines cannot give someone COVID-19 or other illnesses.

- mRNA vaccines do not use any live virus.
- mRNA vaccines cannot cause infection with the virus that causes COVID-19 or other viruses.

They do not affect or interact with our DNA.

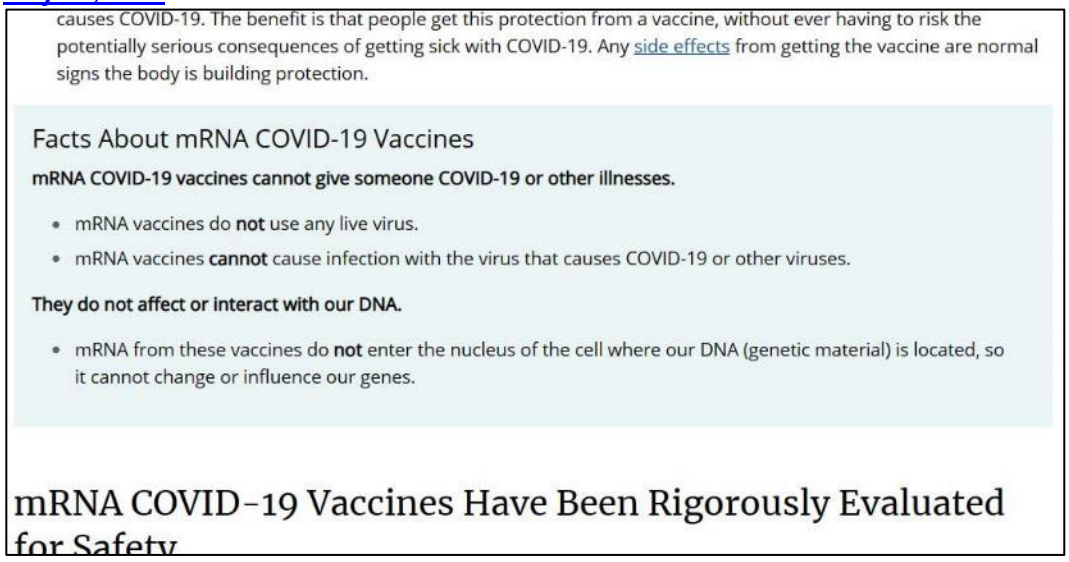
- mRNA from these vaccines do not enter the nucleus of the cell where our DNA (genetic material) is located, so it cannot change or influence our genes.

The mRNA and the spike protein do not last long in the body.

- Our cells break down mRNA from these vaccines and get rid of it within a few days after vaccination.
- Scientists estimate that the spike protein, like other proteins our bodies create, may stay in the body up to a few weeks.

mRNA COVID-19 Vaccines Have Been Rigorously Evaluated for Safety

July 23, 2022



causes COVID-19. The benefit is that people get this protection from a vaccine, without ever having to risk the potentially serious consequences of getting sick with COVID-19. Any side effects from getting the vaccine are normal signs the body is building protection.

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mRNA COVID-19 Vaccines Have Been Rigorously Evaluated for Safety

Note: The citations below are presented in reverse, chronological order.

[640] **ADDED since 2/8/2022**
A Potential Role of the Spike Protein in Neurodegenerative Diseases: A Narrative Review
Cureus
Stephanie Seneff, Anthony M. Kyriakopoulos, Greg Nigh, and Peter A. McCullough
February 11, 2023
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9922164/

"**Abstract**: Human prion protein and prion-like protein misfolding are widely recognized as playing a causal role in many neurodegenerative diseases. Based on *in vitro* and *in vivo* experimental evidence relating to prion and prion-like disease, we extrapolate from the compelling evidence that the spike glycoprotein of SARS-CoV-2 contains extended amino acid sequences characteristic of a prion-like protein to infer its potential to cause neurodegenerative disease. We propose that vaccine-induced spike protein synthesis can facilitate the **accumulation of toxic prion-like fibrils in neurons**. We outline various pathways through which these proteins could be expected to distribute throughout the body. We review both cellular pathologies and the expression of disease that could become more frequent in those who have undergone mRNA vaccination. Specifically, we describe the spike protein's contributions, via its prion-like properties, to **neuroinflammation** and **neurodegenerative diseases**; to **clotting disorders** within the vasculature; to further disease risk due to suppressed prion protein regulation in the context of widely prevalent insulin resistance; and to other health complications. We explain why these prion-like characteristics are more relevant to vaccine-related mRNA-induced spike proteins than natural infection with SARS-CoV-2. We note with an optimism an apparent loss of prion-like properties among the current Omicron variants. We acknowledge that the chain of pathological events described throughout this paper is only hypothetical and not yet verified. We also acknowledge that the evidence we usher in, while grounded in the research literature, is currently largely circumstantial, not direct. Finally, we describe the implications of our findings for the general public, and we briefly discuss public health recommendations we feel need urgent consideration."

[641] **ADDED since 2/8/2022**
A Case Report: Multifocal Necrotizing Encephalitis and Myocarditis after BNT162b2 mRNA Vaccination against COVID-19
Vaccines — Municipal Hospital Dresden-Friedrichstadt, Germany
Michael Mörz
October 1, 2022
https://www.mdpi.com/2076-393X/10/10/1651

"**Abstract**: The current report presents the case of a 76-year-old man with Parkinson's disease (PD) who died three weeks after receiving his third COVID-19 vaccination. The patient was first vaccinated in May 2021 with the ChAdOx1 nCov-19 vector vaccine, followed by two doses of the BNT162b2 mRNA vaccine in July and December 2021. The family of the deceased requested an autopsy due to ambiguous clinical signs before death. PD was confirmed by post-mortem examinations. Furthermore, signs of aspiration pneumonia and systemic arteriosclerosis were evident. However, histopathological analyses of the brain uncovered previously unsuspected findings, including acute vasculitis (predominantly lymphocytic) as well as multifocal necrotizing encephalitis of unknown etiology with

pronounced inflammation including glial and lymphocytic reaction. In the heart, signs of chronic cardiomyopathy as well as mild acute lympho-histiocytic myocarditis and vasculitis were present. Although there was no history of COVID-19 for this patient, immunohistochemistry for SARS-CoV-2 antigens (spike and nucleocapsid proteins) was performed. Surprisingly, only spike protein but no nucleocapsid protein could be detected within the foci of inflammation in both the brain and the heart, particularly in the endothelial cells of small blood vessels. Since no nucleocapsid protein could be detected, **the presence of spike protein must be ascribed to vaccination** rather than to viral infection. The findings corroborate previous reports of encephalitis and myocarditis caused by gene-based COVID-19 vaccines."

[642] **ADDED since 2/8/2022**

Evidence of SARS-CoV-2 spike protein on retrieved thrombi from COVID-19 patients

Journal of Hematology & Oncology — Sapienza University of Rome, Italy
Manuela De Michele, Giulia d'Amati, *et al*.
August 16, 2022
https://jhoonline.biomedcentral.com/articles/10.1186/s13045-022-01329-w

"**Abstract**: The pathophysiology of COVID-19-associated coagulopathy is complex and not fully understood. SARS-CoV-2 spike protein (SP) may activate platelets and interact with fibrin(ogen). We aimed to investigate whether isolated SP can be present in clots retrieved in COVID-19 patients with acute ischemic stroke (by mechanical thrombectomy) and myocardial infarction. In this pilot study, we could detect SP, but not nucleocapsid protein, on platelets of COVID-19 patients' thrombi. In addition, in all three COVID-19 thrombi analyzed for molecular biology, no SARS-CoV-2 RNA could be detected by real-time polymerase chain reaction. These data could support the hypothesis that **free SP**, besides the whole virus, may be the trigger of platelet activation and clot formation in COVID-19."

[643] **ADDED since 2/8/2022**

SARS-CoV-2 S1 Protein Persistence in SARS-CoV-2 Negative Post-Vaccination Individuals with Long COVID/ PASC-Like Symptoms

IncellDx, Inc.
Bruce K. Patterson, Edgar B. Francisco, *et al*.
July 12, 2022
https://www.researchsquare.com/article/rs-1844677/v1

"**Background**: We sought to determine the immunologic abnormalities in patients following SARS-CoV-2 vaccines who experience post-acute sequelae of COVID-19 (PASC)-like symptoms > 4 weeks post vaccination. In addition, we investigated whether the potential etiology was similar to PASC [*a.k.a., long COVID*]…

Results: We determined that **post-vaccination individuals with PASC-like symptoms had similar symptoms to PASC patients**. When analyzing their immune profile, post-vaccination individuals had statistically significant elevations of sCD40L, CCL5, IL-6, and IL-8. **SARS-CoV-2 S1 and S2 protein were detected in CD16 + monocytes** using flow cytometry and mass spectrometry on sorted cells.

Conclusions: Post-vaccination individuals with PASC-like symptoms exhibit markers of platelet activation and pro-inflammatory cytokine production which may be driven by the persistence of SARS-CoV-2 S1 protein persistence in intermediate and non-classical monocytes."

[644] **ADDED since 2/8/2022**

Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination

Cell — Stanford University

Katharina Röltgen, Sandra C.A. Nielsen, *et al*.

March 17, 2022

https://www.cell.com/cell/fulltext/S0092-8674(22)00076-9

"**Summary**: … In contrast to disrupted germinal centers (GCs) in lymph nodes during infection, mRNA vaccination stimulates robust GCs containing vaccine mRNA and spike antigen **up to 8 weeks** postvaccination in some cases."

[645] **ADDED since 2/8/2022**

Persistence of SARS CoV-2 S1 Protein in CD16+ Monocytes in Post-Acute Sequelae of COVID-19 (PASC) up to 15 Months Post-Infection

Frontiers in Immunology — IncellDx, Inc.

January 10, 2022

https://www.frontiersin.org/articles/10.3389/fimmu.2021.746021/full

"The recent COVID-19 pandemic is a treatment challenge in the acute infection stage but the recognition of chronic COVID-19 symptoms termed post-acute sequelae SARS-CoV-2 infection (PASC) may affect up to 30% of all infected individuals. The underlying mechanism and source of this distinct immunologic condition three months or more after initial infection remains elusive. Here, we investigated the presence of SARS-CoV-2 S1 protein in 46 individuals. We analyzed T-cell, B-cell, and monocytic subsets in both severe COVID-19 patients and in patients with post-acute sequelae of COVID-19 (PASC). The levels of both intermediate (CD14+, CD16+) and non-classical monocyte (CD14Lo, CD16+) were significantly elevated in PASC patients up to 15 months post-acute infection compared to healthy controls (P=0.002 and P=0.01, respectively). A statistically significant number of non-classical monocytes contained SARS-CoV-2 S1 protein in both severe (P=0.004) and PASC patients (P=0.02) out to 15 months post-infection…

Discussion: Here, we report the discovery of persistent SARS-CoV-2 protein in CD14lo, CD16+ monocytes out to **15 months** in some individuals and discuss the implications for the pathogenesis of PASC and severe cases of COVID-19."

[646] **Video (4m): *Before your child is injected, watch Dr. Robert Malone's statement on child COVID vaccinations***
Global Covid Summit
Dr. Robert Malone
December 11, 2021
https://globalcovidsummit.org/news/live-stream-event-physicians-alerting-parents

"Before you inject your child - a decision that is irreversible - I wanted to let you know the scientific facts about this genetic vaccine, which is based on the mRNA vaccine technology I created.

There are three issues parents need to understand.

The first is that a viral gene will be injected into your children's cells. This gene forces your child's body to make toxic spike proteins. **These proteins often cause permanent damage in children's critical organs** [*emphasis added*], including

- Their brain and nervous system
- Their heart and blood vessels, including blood clots
- Their reproductive system, and
- This vaccine can trigger fundamental changes to their immune system

The most alarming point about this is that once these damages have occurred, they are irreparable.

- You can't fix the lesions within their brain
- You can't repair heart tissue scarring
- You can't repair a genetically reset immune system, and
- This vaccine can cause reproductive damage that could affect future generations of your family"

[647] ***New VAERS analysis reveals hundreds of serious adverse events that the CDC and FDA never told us about***
Steve Kirsch and Albert Benavides
November 9, 2021
https://stevekirsch.substack.com/p/new-vaers-analysis-reveals-hundreds
Team of Vaccine Safety Experts: https://stevekirsch.substack.com/p/my-team-of-vaccine-safety-experts

For excerpts, see [624]

[648] ***SARS–CoV–2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro***
Viruses journal
Hui Jiang and Ya-Fang Mei
October 13, 2021
https://www.mdpi.com/1999-4915/13/10/2056/htm

"**Abstract**: Here, by using an in vitro cell line, we report that the SARS–CoV–2 spike protein significantly inhibits DNA damage repair, which is required for effective V(D)J recombination in adaptive immunity. Mechanistically, we found that the spike protein **localizes in the nucleus** and **inhibits DNA damage repair by impeding key DNA repair protein BRCA1 and 53BP1 recruitment to the damage site**. Our findings reveal a potential molecular mechanism by which the spike protein might impede adaptive immunity and **underscore the potential side effects of full-length spike-based vaccines** [*emphasis added*]…

3. Results … NHEJ repair and homologous recombination (HR) repair are two major DNA repair pathways that not only continuously monitor and ensure genome integrity but are also vital for adaptive immune cell functions."

3.3. Spike Proteins Impede the Recruitment of DNA Damage Repair Checkpoint Proteins…

To determine how the spike protein inhibits both NHEJ and HR repair pathways, we analyzed the recruitment of BRCA1 and 53BP1, which are the key checkpoint proteins for HR and NHEJ repair, respectively. We found that the spike protein markedly inhibited both BRCA1 and 53BP1 foci formation (Figure 3D–G). Together, these data show that the SARS–CoV–2 full–length spike protein inhibits DNA damage repair by hindering DNA repair protein recruitment."

Notes:

- From this comparative study, Comparison of nonhomologous end joining and homologous recombination in human cells:
  "[W]e conclude that in proliferating cells **NHEJ repairs 75% of DSBs** [*DNA double-strand breaks*] while **HR repairs the remaining 25%** [*emphasis added*]."
- From this study, 53BP1: A key player of DNA damage response with critical functions in cancer:
  "It has been extensively demonstrated that **aberrant expression of 53BP1 contributes to tumor occurrence** and **development**. 53BP1 loss of function in tumor tissues is **also related to tumor progression** and poor prognosis in human malignancies [*emphasis added*]."

[649] ***Why are we vaccinating children against COVID-19?***
Toxicology Reports
Ronald N. Kostoff, Daniela Calina, *et al*.
October 7, 2021
https://www.sciencedirect.com/science/article/pii/S221475002100161X

"**3.1.3.1. Intrinsic inoculant toxicity**: We believe that mid-or long-term adverse effects are possible based on the recent emergence of evidence that would support the probability of mid-and long-term adverse effects from the COVID-19 inoculants, such as:

1) The spike protein itself can be a toxin/pathogenic protein:

2) S protein alone can damage vascular endothelial cells (ECs) by downregulating ACE2 and consequently inhibiting mitochondrial function.

3) it is concluded that ACE2 and endothelial damage is a central part of SARS-CoV2 pathology and may be induced by the spike protein alone.

4) the spike protein of SARS-CoV-1 (without the rest of the virus) reduces ACE2 expression, increases angiotensin II levels, exacerbates lung injury, and triggers cell signaling events that may promote pulmonary vascular remodeling and Pulmonary Arterial Hypertension (PAH) as well as possibly other cardiovascular complications.

5) the recombinant S protein alone elicits functional alterations in cardiac vascular pericytes (PCs)…

12) The spike protein has been found in the plasma of post-inoculation individuals, implying that it could circulate to, and impact adversely, any part of the body.

13) The spike protein of SARS-CoV-2 crosses the blood-brain barrier in mice, and "the SARS-CoV-2 spike proteins trigger a pro-inflammatory response on brain endothelial cells that may contribute to an altered state of BBB function".

14) The spike proteins manufactured in vivo by the present COVID-19 inoculations could potentially "precipitate the onset of autoimmunity in susceptible subgroups, and potentially exacerbate autoimmunity in subjects that have pre-existing autoimmune diseases", based on the finding that anti-SARS-CoV-2 protein antibodies cross-reacted with 28 of 55 diverse human tissue antigens…

3.2. Novel best-case scenario cost-benefit analysis of COVID-19 inoculations for most vulnerable …

The results show ***conservatively*** that there are **five times the number of deaths *truly* attributable to each inoculation vs those *truly* attributable to COVID-19 in the 65+ demographic**. As age decreases, and the risk for COVID-19 decreases, the cost-benefit increases [*emphasis added*]. Thus, if the best-case scenario looks ***poor*** for benefits from the inoculations, any realistic scenario will look ***very poor***. For children the chances of death from COVID-19 are negligible, but the chances of serious damage over their lifetime from the toxic inoculations are not negligible."

[650] ***Open Letter and Notice of Liability from Doctors and Scientists to the EMA and the Members of the European Parliament Regarding COVID-19 Vaccination***
Doctors for COVID Ethics
September 13, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Letter-and-Notice-of-Liability-to-EMA-and-MEPs.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

> "Perhaps the most pertinent finding is that, due to the discovery of a widespread memory-type antibody response to SARS-CoV-2, the antibodies induced by the COVID-19 vaccines can be expected to activate the so-called complement system. This can bring about the destruction of any cell that manufactures the SARS-CoV-2 spike protein, particularly in the circulation. If that happens to the endothelia, that is, the cell layer that lines the inner surfaces of our blood vessels, then those vessels may begin to leak and clots will form. Given that 2021 research showed the spike protein to enter the bloodstream shortly after vaccination, this dangerous endothelial involvement in spike-production is highly likely, and should be expected to occur…
>
> COVID-19 vaccines, on the other hand, are not protein antigens but the genetic blueprint for the SARS-CoV-2 spike protein antigen. That blueprint comes in the form of mRNA or DNA, which, after vaccination, enters our body's cells and instructs those cells to manufacture the spike protein. The spike protein then protrudes from the cell and induces antibody formation. In response, the immune system will react not only with the spike protein, but will **attack and try to destroy the entire cell**…
>
> As well as damage from leakage and clotting alone, it is additionally possible that the vaccine itself may leak into surrounding organs and tissues. Should this take place, the cells of those organs will themselves begin to produce spike protein, and will come under attack in the same way as the vessel walls. Damage to major organs such as the lungs, ovaries, placenta and heart can be expected [*to*] ensue, with increasing severity and frequency as booster shots are rolled out."

[651] ***The SARS-CoV-2 spike protein subunit S1 induces COVID-19-like acute lung injury in K18-hACE2 transgenic mice and barrier dysfunction in human endothelial cells***
American Journal of Physiology
Ruben M.L. Biancatelli, Pavel A. Solopov, *et al*.
August 10, 2021
Note: Figure 3 presents images comparing the lungs of mice injected with SARS-CoV-2 spike proteins and a control group.
https://journals.physiology.org/doi/full/10.1152/ajplung.00223.2021

> "**Results - Spike Protein Elicits "Cytokine Storm" in BALF and Serum**: Mice instilled with S1SP [SARS-CoV-2 spike protein] displayed a cytokine storm in BALF (Fig. 2A) and serum (Fig. 2B), in agreement with the observed neutrophil, monocyte, and macrophage recruitment (Fig. 1D). Minimal cytokine levels were observed in mice exposed to either saline or SP.
>
> **Spike Protein Induces Morphologically Evident ALI and Activates the NF-κB and STAT3 Pathways in the Lungs**: … Figure 3. The S1 subunit of the SARS-CoV-2 spike protein (S1SP) causes acute lung injury and the activation of the STAT3 and NF-κB inflammatory pathways 72 h after exposure."

[652] ***The SARS-CoV-2 Spike protein disrupts human cardiac pericytes function through CD147-receptor-mediated signalling: a potential non-infective mechanism of COVID-19 microvascular disease***
University of Bristol Medical School
Elisa Avolio, Michele Carrabba, *et al*.
July 20, 2021
https://www.biorxiv.org/content/10.1101/2020.12.21.423721v2.full

"**Abstract**: … The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) uses the Spike (S) protein to engage with its receptors and infect host cells. To date, it is still not known whether heart vascular pericytes (PCs) are infected by SARS-CoV-2, and if the S protein alone provokes PC dysfunction. Here, we aimed to investigate the effects of the S protein on primary human cardiac PC signalling and function… In conclusion, our findings suggest that circulating S protein prompts vascular PC dysfunction, potentially contributing to establishing microvascular injury in organs distant from the site of infection…

We provide evidence that cardiac PCs are not infected by SARS-CoV-2. Importantly, we show that the recombinant S protein alone elicits cellular signalling through the CD147 receptor in cardiac PCs, thereby inducing cell dysfunction and microvascular disruption in vitro…

Discussion: Our study provides novel proof-of-concept evidence for S protein to cause molecular and functional changes in human vascular PCs…

In conclusion, although more investigation being needed to definitively prove the harmful effects of the S protein on the heart PCs and associated microvasculature in vivo, this work suggests that fragments of the S protein may elicit vascular cell dysfunction through CD147, independently from the infection. This mechanism has the **potential to spread cellular and organ injury beyond the infection sites** and may have important clinical implications [*emphasis added*]. For instance, in patients with disrupted endothelial barrier and increased vascular permeability due to underlying diseases, such as hypertension, diabetes, and severe obesity, S protein molecules could easily spread to the PC compartment and cause, or exacerbate, microvascular injury."

[653] ***Be aware of SARS-CoV-2 spike protein: There is more than meets the eye***
Journal of Biological Regulators and Homeostatic Agents
TC Theoharides (Tufts University) and P. Conti (University of Chieti, Italy)
June 2021
https://www.biolifesas.org/biolife/wp-content/uploads/2021/06/Theoharides_TC.pdf

"The COVID-19 pandemic necessitated the rapid production of vaccines aimed at the production of neutralizing antibodies against the COVID-19 spike protein required for the corona virus binding to target cells. The best well-known vaccines have utilized either mRNA or an adenovirus vector to direct human cells to produce the spike protein against which the body produces mostly neutralizing antibodies…

… However, recent papers have reported intriguing, but also disturbing, findings concerning **detrimental actions of the spike protein**.

One paper still in preprint stage at Cell reported that certain antibodies in the blood of patients infected with SARS-CoV-2 appear to change the shape of the spike protein so as to make it

more likely to bind to cells and infect them. Evidently, antibodies against the RBD are protective, but antibodies against the N-terminal domain (NTD) induced the open conformation of the RBD enhancing the binding ability and infectivity. Another paper reported that the spike protein shares antigenic epitopes with human molecular chaperons resulting in autoimmunity against endothelial cells. In fact, the spike protein by itself (without being part of the corona virus) was shown to damage endothelium in an animal model via impaired mitochondrial function. A fourth paper reported that the spike protein could alter barrier function in an in-vitro model of the blood-brain barrier (BBB); in particular, the S1 protein promoted loss of barrier ability in an advanced 3D microfluidic model of the buman BBB. Finally, S1 protein was reported to actually cross the BBB and enter the briain of mice, possibly leading to neuroinflammation. In fact, another recent study reported blood vessel damage and inflammation, but no infection, in brains of patients with COVID-19."

[654] ***Circulating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine Recipients***
Clinical Infectious Diseases
Alana F. Ogata, Chi-An Cheng, *et al*.
May 10, 2021
Note: This Harvard study is the first to show evidence that the SARS-CoV-2 spike protein is present systemically in the bloodstream following vaccination, and does not remain localized at the injection site.
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab465/6279075

"**Abstract**: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) proteins were measured in longitudinal plasma samples collected from 13 participants who received two doses of mRNA-1273 vaccine. Eleven of 13 participants showed detectable levels of SARS-CoV-2 protein as early as day 1 after first vaccine injection.

Introduction: … Here we provide evidence that circulating SARS-CoV-2 proteins are present in the plasma of participants vaccinated with the mRNA-1273 vaccine…

Discussion: In this study, 11 participants exhibit S1 antigen in plasma after the first injection, whereas nucleocapsid concentrations are insignificant in all participants, confirming that the detected S1 originates from vaccination and not natural infection…

Nonetheless, evidence of systemic detection of spike and S1 protein production from the mRNA-1273 vaccine is significant and has not yet been described in any vaccine study, likely due to limitations in assay sensitivity and timing assessment. The clinical relevance of this finding is unknown and should be further explored. These data show that **S1 antigen production after the initial vaccination can be detected by day 1 and is present beyond the site of injection** and the associated regional lymph nodes [*emphasis added*]."

[655] ***SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers***
Roxana Bruno, Peter A. Mccullough, *et al*.
May 2021
https://www.researchgate.net/publication/351670290_SARS-CoV-2_mass_vaccination_Urgent_questions_on_vaccine_safety_that_demand_answers_from_international_health_agencies_regulatory_authorities_governments_and_vaccine_developers

See [388]

[656] ***Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19***
International Journal of Vaccine Theory, Practice, and Research
Stephanie Seneff and Greg Nigh
May 10, 2021
https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF~1.PDF

See [389]

[657] ***The novel coronavirus' spike protein plays additional key role in illness. Salk researchers and collaborators show how the protein damages cells, confirming COVID-19 as a primarily vascular disease***
Salk Institute
April 30, 2021
https://www.salk.edu/news-release/the-novel-coronavirus-spike-protein-plays-additional-key-role-in-illness/

> "While the findings themselves aren't entirely a surprise, the paper provides clear confirmation and a detailed explanation of the mechanism through which the protein damages vascular cells for the first time. There's been a growing consensus that SARS-CoV-2 affects the vascular system, but exactly how it did so was not understood. Similarly, scientists studying other coronaviruses have long suspected that the spike protein contributed to damaging vascular endothelial cells, but this is the first time the process has been documented.
>
> In the new study, the researchers created a 'pseudovirus' that was surrounded by SARS-CoV-2 classic crown of spike proteins, but did not contain any actual virus. Exposure to this pseudovirus resulted in damage to the lungs and arteries of an animal model—**proving that the spike protein alone was enough to cause disease**. Tissue samples showed inflammation in endothelial cells lining the pulmonary artery walls [*emphasis added*]."

[658] ***SARS-CoV-2 spike protein alone may cause lung damage***
Medical Xpress
Experimental Biology
April 27, 2021
https://medicalxpress.com/news/2021-04-sars-cov-spike-protein-lung.html

> "Using a newly developed mouse model of acute lung injury, researchers found that exposure to the SARS-CoV-2 spike protein alone was enough to induce COVID-19-like symptoms including severe inflammation of the lungs…
>
> "Our findings show that the SARS-CoV2 spike protein causes lung injury even without the presence of intact virus," said Pavel Solopov, Ph.D., DVM, research assistant professor at the Frank Reidy Research Center for Bioelectrics at Old Dominion University…
>
> The researchers found that the genetically modified mice injected with the spike protein exhibited COVID-19-like symptoms that included severe inflammation, an influx of white blood cells into their lungs and evidence of a cytokine storm—an immune response in which the body starts to attack its own cells and tissues rather than just fighting off the virus."

[659] **ADDED since 2/8/2020**
SARS-CoV-2 Spike Targets USP33-IRF9 Axis via Exosomal miR-148a to Activate Human Microglia
Frontiers in Immunology — National Institute of Immunology, India
Ritu Mishra and Akhil C. Banerjea
April 14, 2021
https://www.frontiersin.org/articles/10.3389/fimmu.2021.656700/full

> "SARS-CoV-2, the novel coronavirus infection has consistently shown an association with neurological anomalies in patients, in addition to its usual respiratory distress syndrome. Multi-organ dysfunctions including neurological sequelae during COVID-19 persist even after declining viral load. We propose that SARS-CoV-2 gene product, Spike, is able to modify the host exosomal cargo, which gets transported to distant uninfected tissues and organs and can **initiate a catastrophic immune cascade within Central Nervous System** (CNS). SARS-CoV-2 Spike transfected cells release a significant amount of exosomes loaded with microRNAs such as miR-148a and miR-590. microRNAs gets internalized by human microglia and suppress target gene expression of USP33 (Ubiquitin Specific peptidase 33) and downstream IRF9 levels. Cellular levels of USP33 regulate the turnover time of IRF9 via deubiquitylation. Our results also demonstrate that absorption of modified exosomes effectively regulate the major pro-inflammatory gene expression profile of TNFα, NF-κB and IFN-β. These results uncover a bystander pathway of SARS-CoV-2 mediated CNS damage through hyperactivation of human microglia. Our results also attempt to explain the extra-pulmonary dysfunctions observed in COVID-19 cases when active replication of virus is not supported. Since Spike gene and mRNAs have been extensively picked up for vaccine development; the knowledge of host immune response against spike gene and protein holds a great significance. Our study therefore provides novel and relevant insights regarding the impact of Spike gene on shuttling of host microRNAs via exosomes to trigger the neuroinflammation."

[660] ***SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2***
Circulation Research (Salk Institute)
Yuyang Lei, Jiao Zhang, *et al*.
March 31, 2021
https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.121.318902

Includes images of "[r]epresentative images of vascular endothelial control cells (left) and cells treated with the SARS-CoV-2 Spike protein (right) [which] show that the spike protein causes increased mitochondrial fragmentation in vascular cells."

"SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) infection relies on the binding of S protein (Spike glycoprotein) to ACE (angiotensin-converting enzyme) 2 in the host cells. Vascular endothelium can be infected by SARS-CoV-2, which triggers mitochondrial reactive oxygen species production and glycolytic shift. Paradoxically, ACE2 is protective in the cardiovascular system, and SARS-CoV-1 S protein promotes lung injury by decreasing the level of ACE2 in the infected lungs. In the current study, we show that **S protein alone can damage vascular endothelial cells** (ECs) by downregulating ACE2 and consequently inhibiting mitochondrial function [*emphasis added*]."

[661] ***Review of COVID-19 Vaccines and the Risk of Chronic Adverse Events Including Neurological Degeneration***
Journal of Medical-Clinical Research & Reviews
J. Bart Classen
March 24, 2021
https://scivisionpub.com/pdfs/review-of-covid19-vaccines-and-the-risk-of-chronic-adverse-events-including-neurological-degeneration-1616.pdf

"**Abstract**: Many have argued that the outbreak of COVID-19 is the result of the release of a viral based bioweapon. Vaccines to COVID-19 have been developed and a policy of universal immunization has been initiated with total disregard to the fact that the virus may be a bioweapon. The potential risk of a catastrophe exists in part because all the vaccines contain the spike protein and or the mRNA/DNA encoding for the COVID-19 associated spike protein. These vaccines were designed and placed on the market with little knowledge of how the spike protein or its nucleic acid causes disease and without knowledge of long-term adverse effects of the vaccines. This paper reviews many of the potential long-term risks that could result from receiving one of the COVID-19 vaccines. The potential for the spike protein and its mRNA to cause **prion disease** is reviewed as well as reasons why the vaccine could be much more dangerous than the natural infection. Adenoviral derived COVID-19 vaccines are particularly risky because of their potential to recombine with human DNA or viruses already in the human recipient. The result could be new infectious adenoviral species containing spike proteins that could infect humans and farm animals used for food. Some of the COVID-19 vaccines utilize novel technology including nanotechnology and novel adjuvants that increase intracellular penetration of cells and can potentially exacerbate chronic toxicity from the spike protein. Governments should consider suspending sale of the COVID-19 vaccines until they have a better understanding of their risks."

[662] ***SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines***
Vaccines journal
Yuichiro J. Suzuki and Sergiy G. Gychka
January 11, 2021
https://www.mdpi.com/2076-393X/9/1/36/htm

"**3. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Cells**

It was found that the treatment of cultured primary human pulmonary artery smooth muscle cells (SMCs) or human pulmonary artery endothelial cells with the recombinant SARS-CoV-2 spike protein S1 subunit is sufficient to promote cell signaling without the rest of the viral components. Furthermore, our analysis of the postmortem lung tissues of patients who died of COVID-19 has determined that these patients exhibited pulmonary vascular wall thickening, a hallmark of pulmonary arterial hypertension (PAH). Based on these results, we proposed that the SARS-CoV-2 spike protein (without the rest of the viral components) triggers cell signaling events that may promote **pulmonary vascular remodeling** and **PAH** as well as possibly other **cardiovascular complications** [*emphasis added*]…

These results collectively reinforce the idea that human cells are sensitively affected by the extracellular and/or intracellular spike proteins though the activation of cell signal transduction…

6. Discussion…

[I]t is important to consider the possibility that the SARS-CoV-2 spike protein produced by the new COVID-19 vaccines triggers cell signaling events that promote PAH, other cardiovascular complications, and/or complications in other tissues/organs in certain individuals (Figure 3). We will need to monitor carefully the long-term consequences of COVID-19 vaccines that introduce the spike protein into the human body. Furthermore, while **human data on the possible long-term consequences of spike protein-based COVID-19 vaccines will not be available soon** [*emphasis added*], it is imperative that appropriate experimental animal models are employed as soon as possible to ensure that the SARS-CoV-2 spike protein does not elicit any signs of the pathogenesis of PAH or any other chronic pathological conditions."

[663] ***Docked severe acute respiratory syndrome coronavirus 2 proteins within the cutaneous and subcutaneous microvasculature and their role in the pathogenesis of severe coronavirus disease 2019***
Human Pathology
Cynthia M. Magro, J. Justin Mulvey, *et al*.
December 2020
https://www.sciencedirect.com/science/article/abs/pii/S0046817720302008?via%3Dihub

"**Summary**: The purpose of this study was to examine the deltoid skin biopsy in twenty-three patients with coronavirus disease 2019 (COVID-19), most severely ill, for vascular complement deposition and correlate this with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA and protein localization and ACE2 expression… The dominant microvascular complement immunoreactant identified was the terminal membranolytic attack complex C5b-9. Microvascular complement deposition strongly colocalized *in situ* with the SARS-CoV-2 viral proteins including spike glycoproteins in the endothelial cells…"

[664] ***The SARS-CoV-2 spike protein alters barrier function in 2D static and 3D microfluidic in-vitro models of the human blood–brain barrier***
Neurobiology of Disease
Tetyana P. Buzhdygan, Brandon J. DeOre, *et al*.
December 2020
https://www.sciencedirect.com/science/article/pii/S096999612030406X?via%3Dihub

"**Abstract**: [T]he results presented in this report explored whether deleterious outcomes from the SARS-CoV-2 viral spike protein on primary human brain microvascular endothelial cells (hBMVECs) could be observed… Evidence provided suggests that the SARS-CoV-2 spike proteins trigger a pro-inflammatory response on brain endothelial cells that may contribute to an altered state of BBB [*blood-brain barrier*] function. Together, these results are the first to show the direct impact that the SARS-CoV-2 spike protein could have on brain endothelial cells; thereby offering a plausible explanation for the neurological consequences seen in COVID-19 patients."

[665] ***SARS-CoV-2 Spike Protein and Lung Vascular Cells***
Journal of Respiration (Georgetown University Medical Center)
Sri Jayalakshmi Suresh and Yuichiro Justin Suzuki
December 31, 2020
https://www.mdpi.com/2673-527X/1/1/4/htm

"**3. Pathology of PAH**

PAH [*pulmonary arterial hypertension*] is a fatal disease without a cure that can affect both males and females of any age, including children. It is a progressive disease, and by the time patients are diagnosed, the thickening of the pulmonary vascular walls has often already occurred. Increased resistance in the pulmonary circulation places strain on the right ventricle, which leads to right heart failure and death. The median overall survival for patients with PAH is 2.8 years from the time of diagnosis (three-year survival: 48%) without treatment. Even with currently available therapies, the prognosis remains poor, with a three-year survival of PAH patients reported to be only 58–75%...

7. COVID-19 Vaccines and PAH

COVID-19 vaccines currently under consideration, including RNA vaccines (BNT162b2 and mRNA-1273), viral vector-based vaccines (AZD1222 and Ad26.COV2.S), and recombinant protein (NVX-CoV2373), all introduce the SARS-CoV-2 spike protein into the human body. Whether the spike protein elicits cell signaling in host cells and exerts adverse events such as promoting PAH is a question raised in response to the experimental results in cultured cells. RNA and viral vector-based vaccines use human host cells to produce the spike protein; thus, the intracellular spike protein will be produced. **The intracellular effects of this foreign molecule on human cells have not been defined** [*emphasis added*]…

8. Conclusions

This analysis suggests that the SARS-CoV-2 spike protein and HIV gp120 have the capacity to trigger cell biological events that may lead to the development of pulmonary vascular remodeling and, perhaps, clinically significant PAH, a fatal condition. Given the observations that cells sensitively respond to the spike protein at pM concentrations in cultured cells, **it is**

likely that the SARS-CoV-2 spike protein not only facilitates the viral entry and serves to acquire immunity as an antigen for vaccines but, also, **targets host cells and may exert adverse effects** (Figure 4). Further experiments should be performed to address the possible effects of the SARS-CoV-2 spike protein on developing PAH. The effects of the SARS-CoV-2 spike protein on the cells of other tissues/organs, such as those of the systemic vasculature, heart, and brain, should also be investigated. Given that this protein will be administered as vaccines to millions and possibly billions of people, it is critical to understand the extracellular and intracellular effects of the SARS-CoV-2 spike protein on human cells that **may promote long-term adverse health consequences** [*emphasis added*]."

[666] ***The S1 protein of SARS-CoV-2 crosses the blood–brain barrier in mice***
Nature magazine
Elizabeth M. Rhea, Aric F. Logsdon, *et al*.
December 16, 2020
https://www.nature.com/articles/s41593-020-00771-8

"**Abstract**: It is unclear whether severe acute respiratory syndrome coronavirus 2, which causes coronavirus disease 2019, can enter the brain. Severe acute respiratory syndrome coronavirus 2 binds to cells via the S1 subunit of its spike protein. We show that **intravenously injected radioiodinated S1 (I-S1) readily crossed the blood–brain barrier** in male mice, was taken up by brain regions and entered the parenchymal brain space [*emphasis added*]. I-S1 was also taken up by the lung, spleen, kidney and liver."

[667] ***A Multibasic Cleavage Site in the Spike Protein of SARS-CoV-2 Is Essential for Infection of Human Lung Cells***
Molecular Cell
Markus Hoffman, Hanna Kliene-Weber, and Stefan Pohlmann
May 1, 2020
https://www.cell.com/molecular-cell/fulltext/S1097-2765(20)30264-1

"**Summary**: The pandemic coronavirus SARS-CoV-2 threatens public health worldwide. The viral spike protein mediates SARS-CoV-2 entry into host cells and harbors a S1/S2 cleavage site containing multiple arginine residues (multibasic) not found in closely related animal coronaviruses. However, the role of this multibasic cleavage site in SARS-CoV-2 infection is unknown. Here, we report that the cellular protease furin cleaves the spike protein at the S1/S2 site and that **cleavage is essential for S-protein-mediated cell-cell fusion** and **entry into human lung cells** [*emphasis added*]… Our results suggest that acquisition of a S1/S2 multibasic cleavage site was essential for SARS-CoV-2 infection of humans and identify furin as a potential target for therapeutic intervention."

[668] ***Two Mutations Were Critical for Bat-to-Human Transmission of Middle East Respiratory Syndrome Coronavirus***
Journal of Virology
Yang Yang, Chang Liu, Lanying Du, Shibo Jiang, Zhengli Shi, Ralph S. Baric, and Fang Li
September 2015
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_dd79a86de7064bb29f9b3d2165063af8.pdf

> "To understand how Middle East respiratory syndrome coronavirus (MERS-CoV) transmitted from bats to humans, we compared the virus surface spikes of MERS-CoV and a related bat coronavirus, HKU4. Although HKU4 spike cannot mediate viral entry into human cells, two mutations enabled it to do so by allowing it to be activated by human proteases...
>
> To evaluate the potential genetic changes required for HKU4 to infect human cells, we **reengineered HKU4 spike**, aiming to build its capacity to mediate viral entry into human cells [*emphasis added*]. To this end, we introduced two single mutations, S746R and N762A, into HKU4 spike. The S746R mutation was expected to restore the hPPC motif in HKU4 spike, whereas the N762A mutation likely disrupted the potential N-linked glycosylation site in the hECP motif in HKU4 spike. To confirm that the S746R mutation restored the hPPC motif, we produced retroviruses pseudotyped with HKU4 spike (referred to as HKU4 pseudoviruses) in human cells… Moreover, mutations in these motifs in coronavirus spikes have demonstrated dramatic effects on viral entry into human cells."

Antibody Dependent Enhancement (ADE)

[669] **ADDED since 2/8/2022**
Antibody-dependent enhancement
The Free Medical Dictionary
https://encyclopedia.thefreedictionary.com/Antibody+dependent+enhancement

> "**Antibody-dependent enhancement (ADE)**, sometimes less precisely called immune enhancement or disease enhancement, is a phenomenon in which binding of a virus to suboptimal antibodies enhances its entry into host cells, followed by its replication…
>
> ADE may cause enhanced respiratory disease and acute lung injury after respiratory virus infection (ERD) with symptoms of monocytic infiltration and an excess of eosinophils in respiratory tract. ADE along with type 2 T helper cell-dependent mechanisms may contribute to a development of the vaccine associated disease enhancement (VADE), which is not limited to respiratory disease. Some vaccine candidates that targeted coronaviruses, RSV virus and Dengue virus elicited VADE, and were terminated from further development or became approved for use only for patients who have had those viruses before…
>
> VADE might hamper vaccine development, as a vaccine may trigger the production of antibodies which, via ADE and other mechanisms, worsen the disease the vaccine is designed to protect against. This was a concern during late clinical stages of vaccine development against COVID-19."

Note: The citations below are presented in reverse, chronological order.

[670] **Video (9m): *Expert testimony of Dr. Christina Parks, PhD***
Michigan House of Representatives hearing
August 25, 2021
https://rumble.com/vloa7j-must-watch-expert-testimony-on-mandatory-vaccination-and-medical-coercion.html

> **Parks (starting at 5:05)**: "Vaccines are made to a specific variant, and when that variant mutates, the vaccine no longer recognizes it. So it's like you're seeing a completely new virus. And because that's so, you actually get more severe symptoms when you're vaccinated against one variant, and then it mutates, and then your body sees the other variant. So there's the potential, and the science shows, that in fact with the flu, if you get vaccinated in multiple years, you are more likely to get severe disease, you are more likely to have more viral replication, and you are more likely to be hospitalized...
>
> We are seeing the same thing in COVID with the delta variant. And so we are mandating that people get a vaccine that could actually make them more sick when they're exposed to the virus? In fact, this week, a paper came out, and what it showed is that with this delta variant, when you're vaccinated, your body makes antibodies that are supposed to neutralize the virus. But they were supposed to neutralize the old variant. When they see this new variant, what they're doing is, the **antibodies are actually taking the virus and helping it infect the cells** [*emphasis added*]."

[671] **Letter to the Editor: *Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination?***
Journal of Infection
Nouara Yahi, Henri Chahinian, and Jacques Fantini
August 9, 2021
https://www.journalofinfection.com/article/S0163-4453(21)00392-3/fulltext

> "In conclusion, ADE may occur in people receiving vaccines based on the original Wuhan strain spike sequence (either mRNA or viral vectors) and then exposed to a Delta variant… [T]he possibility of ADE should be further investigated as it may represent a potential risk for mass vaccination during the current Delta variant pandemic."

[672] **Video (10m): Interview with Dr. Robert Malone, inventor of some important mRNA-vaccine technology**
July 28, 2021
https://rumble.com/vkfz1v-the-vaccine-causes-the-virus-to-be-more-dangerous.html

> **Malone**: "The escaped mutants that are escaping vaccine-selected pressure are most likely developing in the people that have been vaccinated, not in the unvaccinated… What you heard Fauci say is the nasal titers are the same in vaccine recipients and unvaccinated… What NBC News dropped yesterday was the statement sourced from an unnamed government official that the titers in the vaccinated are actually higher than in the unvaccinated… This is precisely what one would see if **Antibody Dependent Enhancement** was happening… (which) is where the vaccine causes the virus to become more infectious than would happen in the absence of vaccination, would cause the virus to replicate at higher levels than in the absence of infection. This is the vaccinologists' worst nightmare… I don't mean to sound alarmist, but what seems to be rolling out is the worst-case scenario where a vaccine (Pfizer), in the waning phase, is causing the virus to replicate more efficiently than it would otherwise, which is what we call Antibody Dependent Enhancement… and people have been warning about this since the outset of this rushed vaccine campaign."

[673] ***SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers***
Roxana Bruno, Peter A. Mccullough, *et al*.
May 2021
https://www.researchgate.net/publication/351670290_SARS-CoV-2_mass_vaccination_Urgent_questions_on_vaccine_safety_that_demand_answers_from_international_health_agencies_regulatory_authorities_governments_and_vaccine_developers

See [388]

[674] ***An infectivity-enhancing site on the SARS-CoV-2 spike protein targeted by antibodies***
Cell
Yafei Liu, Wai Tuck Soh, *et al*.
May 24, 2021
https://www.cell.com/cell/fulltext/S0092-8674(21)00662-0

"**Discussion**: Antibody-dependent enhancement (ADE) of viral infection has been reported for some viruses such as dengue virus (Wan et al., 2020), feline infectious peritonitis virus (FIPV) (Hohdatsu et al., 1998; Vennema et al., 1990), severe acute respiratory syndrome coronavirus (SARS) (Jaume et al., 2011; Kam et al., 2007), and Middle East respiratory syndrome (MERS) (Wan et al., 2020). Binding of the Fc receptor to anti-virus antibodies complexed with virions has been thought to be involved in ADE (Wang et al., 2017). However, Fc-receptor-mediated ADE is restricted to the infection of Fc-receptor-expressing cells such as monocytes or macrophages. In this study, we found a non-canonical, Fc-receptor-independent ADE mechanism. The antibodies against a specific site on the NTD of the SARS-CoV-2 spike protein were found to directly augment the binding of ACE2 to the spike protein, consequently increasing SARS-CoV-2 infectivity."

[675] ***Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19***
International Journal of Vaccine Theory, Practice, and Research
Stephanie Seneff and Greg Nigh
May 10, 2021
https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF~1.PDF

See [389]

[676] ***Doctors and Scientists Write to the European Medicines Agency, Warning of COVID-19 Vaccine Dangers for a Third Time***
Doctors for COVID Ethics
April 24, 2021
https://doctors4covidethics.org/doctors-and-scientists-write-to-the-european-medicines-agency-warning-of-covid-19-vaccine-dangers-for-a-third-time/
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"1e. Furthermore, long term adverse effects, in particular the danger of **immune dependant** [*sic*] **enhancement** of disease and adverse effects of subsequent vaccinations are impossible to predict. The European Medicines Agency, as the regulator re. vaccines for almost 450 million people across 27 European Union member states, must inform the public and the relevant authorities of this profoundly important issue."

[677] ***COVID-19 Vaccine: Critical Questions with Complicated Answers***
Biomolecules & Therapeutics
Mohammad Faisal Haidere, Zubair Ahmed Ratan, *et al*.
January 1, 2021
https://www.biomolther.org/journal/view.html?volume=29&number=1&spage=1&year=2021

> "[E]xtreme caution must be taken to scrutinize backfire-effects i.e. the undesirable adverse effects (Table 2). **One such dangerous backfire is vaccine-induced enhancement**, which has been a major bottleneck in the development of certain corona-, flavi-, lenti-, and paramyxovirus vaccines. Here, antibody-dependent enhancement (ADE) performs a key role (Huisman et al., 2009). One study reported that the recombinant vaccinia virus Ankara expressing the S protein of SARS-CoV increased hepatitis in ferrets (Weingartl et al., 2004). Anti-S protein IgG against SARS-CoV caused severe acute lung injury in macaques (Liu et al., 2019). New Zealand white rabbits displayed increased lung inflammation after re-infection with MERS-CoV due to the lack of non-neutralizing antibodies and complement proteins (Houser et al., 2017). Researchers assume that SARS-CoV-2 severity is a consequence of ADE (Tetro, 2020). However, a study opined that the ADE and immunopathology are linked to the inflammatory feedback of host Th17, and this can be overcome by using alum as an adjuvant (Hotez et al., 2020). Now, the question arises. Will it be possible to overcome the backfires in developing COVID-19 vaccine? In brief, researchers need to resolve these questions to develop effective and safe vaccines against COVID-19 infection."

[678] ***FDA Briefing Document - Moderna COVID-19 Vaccine***
Food and Drug Administration (FDA)
December 17, 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_2b26a980a8d44de89cd21c42af406565.pdf

> "**Vaccine-enhanced disease**. Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, **risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown** and needs to be evaluated further in ongoing clinical trials and in observational studies [*emphasis added*] that could be conducted following authorization and/or licensure."

[679] **FDA Briefing Document: *Vaccines and Related Biological Products Advisory Committee Meeting***
Food and Drug Administration (FDA)
December 10, 2020
https://www.fda.gov/media/144245/download

> "**8.4. Unknown Risks/Data Gaps... Vaccine-enhanced disease** - Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, **risk of vaccine-enhanced disease** over time, potentially associated with waning immunity, **remains unknown** and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure."

[680] ***Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease***
International Journal of Clinical Practice
Timothy Cardazo and Ronald Veazey
December 4, 2020
https://pubmed.ncbi.nlm.nih.gov/33113270/

"**Results of the study**: COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the development and testing of these vaccines suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE). This risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials.

Conclusions drawn from the study and clinical implications: The **specific and significant COVID-19 risk of ADE** should have been and should be prominently and independently disclosed to research subjects currently in vaccine trials, as well as those being recruited for the trials and future patients after vaccine approval [*emphasis added*], in order to meet the medical ethics standard of patient comprehension for informed consent."

[681] ***Antibody-dependent enhancement and SARS-CoV-2 vaccines and therapies***
Nature Microbiology
Wen Shi Lee, Adam K. Wheatley, Stephen J. Kent, and Brandon J. DeKosky
September 9, 2020
https://www.nature.com/articles/s41564-020-00789-5

"**Abstract**: … Data from the study of SARS-CoV and other respiratory viruses suggest that anti-SARS-CoV-2 antibodies could exacerbate COVID-19 through antibody-dependent enhancement (ADE). Previous respiratory syncytial virus and dengue virus vaccine studies revealed human clinical safety risks related to ADE, resulting in failed vaccine trials…

Risk of ERD for SARS-CoV-2 vaccines: Safety concerns for SARS-CoV-2 vaccines were initially fuelled [sic] by mouse studies that showed enhanced immunopathology, or ERD, in animals vaccinated with SARS-CoV following viral challenge…

Should it occur, ERD caused by human vaccines will first be observed in larger phase II and/or phase III efficacy trials that have sufficient infection events for statistical comparisons between the immunized and placebo control study arms…

Conclusion: ADE has been observed in SARS, MERS and other human respiratory virus infections including RSV and measles, which suggests a **real risk of ADE for SARS-CoV-2 vaccines** and antibody-based interventions… Going forwards, it will be crucial to evaluate animal and clinical datasets for signs of ADE, and to balance ADE-related safety risks against intervention efficacy if clinical ADE is observed."

[682] **ADDED since 2/8/2022**

ADE and hyperinflammation in SARS-CoV2 infection- comparison with dengue hemorrhagic fever and feline infectious peritonitis

Cytokine — Université de Sherbrooke, Canada

Maryse Cloutier, Madhuparna Nandi, *et al*.

August 28, 2020

https://www.sciencedirect.com/science/article/pii/S1043466620302726

"**Abstract**: The COVID-19 pandemic has rapidly spread around the world with significant morbidity and mortality in a subset of patients including the elderly. The poorer outcomes are associated with 'cytokine storm-like' immune responses, otherwise referred to as 'hyperinflammation'. While most of the infected individuals show minimal or no symptoms and recover spontaneously, a small proportion of the patients exhibit severe symptoms characterized by extreme dyspnea and low tissue oxygen levels, with extensive damage to the lungs referred to as acute respiratory distress symptom (ARDS). The consensus is that the hyperinflammatory response of the host is akin to the cytokine storm observed during sepsis and is the major cause of death. Uncertainties remain on the factors that lead to hyperinflammatory response in some but not all individuals. Hyperinflammation is a common feature in different viral infections such as dengue where existing low-titer antibodies to the virus enhances the infection in immune cells through a process called antibody-dependent enhancement or ADE. **ADE has been reported following vaccination** or secondary infections with other corona, Ebola and dengue virus. Detailed analysis has shown that antibodies to any viral epitope can induce ADE when present in sub-optimal titers or is of low affinity. In this review we will discuss ADE in the context of dengue and coronavirus infections including Covid-19…

2.2. ADE in Coronaviridae: Pathogenic members of the Coronavirus family infect primarily the epithelial cells in the respiratory and gastrointestinal tracts. Among the various members, immune responses have been well characterized *in vivo* in cats following natural infection with feline corona virus…

Immunization with vaccinia virus expression the Spike protein generated low titer of antibodies in kittens and accelerated the disease following challenge with the virulent virus by ADE. Again, transfer of antibodies from FIP [*feline infectious peritonitis virus*] or seropositive healthy cats accelerated the disease process following infection of recipients. The role of pre-existing antibodies is not clear as vaccination with low virulent with ORF3abc truncated strain of FCoV induced comparable neutralizing antibodies in SPF-reared [*specific pathogen free*] and conventional cat. However, protection from subsequent lethal challenge was seen only in cats reared in SPF but not in conventional facilities. As the 2 strains of cats were different in this study it is not possible to arrive at conclusions by comparing the 2 groups. Nonetheless, cats that showed high titers following vaccination **succumbed at later timepoints to fatal disease** supporting a protective role of high titer neutralizing antibodies in keeping viremia under check."

[683] **ADDED since 2/8/2022**

The 2020 Pandemic: Current SARS-CoV-2 Vaccine Development

Frontiers in Immunology — Drexel University College of Medicine

Sana O. Alturki, Sawsan O. Alturki, *et al*.

August 19, 2020

https://www.frontiersin.org/articles/10.3389/fimmu.2020.01880/full

"**Antibody Dependent Enhancement (ADE): A Potential Hurdle for Coronavirus Vaccine Development:** Due to the presence of different strains of coronavirus and the strong structural homology between the two RBD of SARS-CoV and SARS-CoV-2, the cross-reactivity between antibodies of different coronaviruses must be taken into consideration for SARS-CoV-2 vaccine development. Antibodies have a dual role in controlling infections in which either they neutralize the infection or enhance pathogen uptake. Several viruses rely on pre-existing antiviral antibodies for their entry into the target cells, a mechanism known as antibody-dependent enhancement (ADE). Pre-existing antiviral antibodies from heterologous strains can prevent the virus entry to the cells by blocking the binding to its natural receptor on the host cell surface. However, these antibodies could facilitate the entry of the virus to host cells through either interaction of the antibody-virus complex with FcR receptors on various immune cells or complement receptors by activating the complement classical pathway. Both mechanisms tend to be linked to disease exacerbation. Generally, **ADE educes** sustained inflammation, lymphopenia, and potentially, cytokine storm, causing severe illness, or **death**. Furthermore, ADE has been observed in a variety of viruses including flaviviruses, HIV, and Ebola virus. Importantly, ADE has been extensively studied in dengue viral infections since ADE has been linked to the severity of dengue shock syndrome. It should be noted that ADE was linked to some vaccines, as this was demonstrated in the efficacy trials of the tetravalent dengue vaccine (CYD-TDV). In the CYD-TDV trial, they found that seronegative individuals who received CYD-TDV suffered severe dengue disease that mimics the natural secondary infection unlike seropositive individuals who had been exposed to dengue before vaccination.

Recently, a study demonstrated that ADE occurs not only through the typical mechanism of the presence of sub-neutralizing antibodies but also that neutralizing antibodies against RBD [*receptor binding domain*] might be involved in ADE. This mechanism depends on the affinity, the amount, and the specificity of the antibodies. Furthermore, from a different group, the cross reactivity of anti-RBD polyclonal antibodies specific for SARS-CoV with RBD protein of SARS-CoV-2 pseudovirus was demonstrated. Moreover, ADE phenomena have been identified in SARS-CoV infections, and now potentially COVID-19. It could be hypothesized that ADE has a role in the high mortality rate in China.

The high mortality rate in some countries over the others could be due to prior exposure of one or more mild strains of similar coronaviruses. The data obtained from patients of Hubei region showed lymphopenia and sustained inflammation in most of the severe and death cases. Based on the previous information, individuals suffering the most severe disease of COVID-19 may experience the effects of antibody dependent enhancement (ADE). ADE as a complication of COVID19 should be at the forefront while developing SARS-COV-2 vaccines to avoid similar mistakes in other vaccine development like the dengue vaccine"

[684] **Correspondence: *Implications of antibody-dependent enhancement of infection for SARS-CoV-2 countermeasures***
Nature Biotechnology
Nikolai Eroshenko, Taylor Gill, Marianna K. Keaveney, George M. Church, Jose M. Trevejo, and Hannu Rajaniemi
June 5, 2020
https://www.nature.com/articles/s41587-020-0577-1

> "ADE has been observed with dengue virus, Zika virus, Ebola virus and, importantly in the context of COVID-19, coronaviruses (CoVs)… We believe that it is important to consider ADE in the context of efforts to develop countermeasures against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). Indeed, data from previous CoV research strongly suggest that ADE may play a role in the virus's pathology…
>
> Although efficacy data on human CoV vaccines are lacking, results from preclinical models suggest that certain vaccine designs are more likely to induce ADE immune responses than others…
>
> In fact, preclinical studies employing various animals, including mice, hamsters, ferrets and macaques, **provided evidence that SARS-CoV vaccines are capable of causing an ADE response**…
>
> Although the development of vaccines and therapeutics for SARS-CoV-2 remains urgent, we must proceed with caution, using the full armory of vaccine and protein design tools at our disposal to rationally minimize the risk of ADE."

[685] **ADDED since 2/8/2022**
Video (2m): ***Fauci on Antibody Dependent Enhancement (ADE)***
Mark Zuckerberg interview with Anthony Fauci
March 2020
https://rumble.com/v13ewa5-fauci-on-antibody-dependent-enhancement-ade.html

> **Fauci**: "There's another element ot safety, and that is if you vaccinate someone and they make an antibody response, and then they get exposed and infected, does the response that you induce actually enhance the infection and make it worse. And the only way you'll know that is if you do an extended study, not in a normal volunteer who has no risk of infection, but in people who are out there in a risk situation.
>
> This would not be the first time if it happened that a vaccine that looked in initial safety actually made people worse. There was the history of the respiratory interstitial virus vaccine in children, which paradoxically made the children worse. One of the HIV vaccines that we tested several years ago actually made individuals more likely to get infected. So you can't just go out there and give it unless you feel that in the field, when someone is getting infected and exposed, being vaccinated doesn't make them worse. That's why you gotta do a trial."

[686] **Science Committee hearing: Testimony of Dr. Peter Hotez**
US House of Representatives
March 5, 2020
https://www.c-span.org/video/?c4873497/user-clip-hotez-coronavirus-vaccine-safety-testimony

> Hotez: "One of the things we're not hearing a lot about is the unique, potential safety problem of coronavirus vaccines. This was first found in the early 1960s with the respiratory syncytial virus vaccines in children, and it was done here in Washington at NIH and the Children's National Medical Center, that some of those kids who got the vaccine actually did worse, and I believe there were two deaths as a consequence of that study. Because what happens with certain types of respiratory-virus vaccines, you get immunized and then when you get actually exposed to the virus, you get this kind of paradoxical, **immune enhancement phenomenon**… When we started developing coronavirus vaccines and our colleagues, we noticed in laboratory animals that they started to show some of the same immune pathology that resembled what had happened 50 years earlier. It was, 'Oh my god, this is going to be problematic.'… The clinical trials are not going to go quickly because of that immune enhancement."

[687] ***Viral-Induced Enhanced Disease Illness***
Frontiers in Microbiology
Maria K. Smatti, Asmaa A. Al Thani, and Hadi M. Yassine
December 5, 2018
Includes an overview of clinical studies for past SARS-CoV vaccines.
https://www.frontiersin.org/articles/10.3389/fmicb.2018.02991/full

> "**Abstract**: … Considering that antibody dependent enhancement (ADE) is a major obstacle in vaccine development, there are continued efforts to understand the underlying mechanisms through identification of the epitopes and antibodies responsible for disease enhancement or protection. This review discusses the recent findings on virally induced ADE, and highlights the potential mechanisms leading to this condition…
>
> **Coronaviruses**: … Several studies have investigated the mechanisms underlying SARS-CoV mediated ADE."

[688] ***Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS Virus***
PLOS One
Chien-Te Tseng, Elena Sbrana, *et al*.
April 20, 2012
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0035421

> "**Results**: … All mice exhibited histopathologic changes in lungs two days after challenge including all animals vaccinated (Balb/C and C57BL/6) or given live virus, influenza vaccine, or PBS suggesting infection occurred in all. Histopathology seen in animals given one of the SARS-CoV vaccines was uniformly a Th2-type immunopathology with prominent eosinophil infiltration, confirmed with special eosinophil stains…
>
> **Conclusions**: These SARS-CoV vaccines all induced antibody and protection against infection with SARS-CoV. However, challenge of mice given any of the vaccines led to occurrence of Th2-type immunopathology suggesting hypersensitivity to SARS-CoV

components was induced. Caution in proceeding to application of a SARS-CoV vaccine in humans is indicated…

Experiments: … Representative photo micrographs of lung sections from mice in this experiment two days after challenge with SARS-CoV are shown in figure 5. The pathologic changes were extensive and similar in all challenged groups (H & E stains). Perivascular and peribronchial inflammatory infiltrates were observed in most fields along with desquamation of the bronchial epithelium, collections of edema fluid, sloughed epithelial cells, inflammatory cells and cellular debris in the bronchial lumen. Large macrophages and swollen epithelial cells were seen near lobar and segmental bronchi, small bronchioles and alveolar ducts. Necrotizing vasculitis was prominent in medium and large blood vessels, involving vascular endothelial cells as well as the tunica media, and included lymphocytes, neutrophils, and eosinophils in cellular collections. Occasional multinucleated giant cells were also seen."

[689] ***A Double-Inactivated Severe Acute Respiratory Syndrome Coronavirus Vaccine Provides Incomplete Protection in Mice and Induces Increased Eosinophilic Proinflammatory Pulmonary Response upon Challenge***
Journal of Virology
Meagan Bolles, Damon Deming, *et al*.
November 3, 2011
https://journals.asm.org/doi/10.1128/JVI.06048-11

"**Discussion**: ... The development of vaccines or therapeutics for SARS-CoV is complicated by several challenges: the presence of a large heterogeneous zoonotic reservoir of related strains, the resistance of highly susceptible aged populations to vaccination, and potential **disease-enhancing complications** of the vaccine formulations [*emphasis added*]…

As shown here, a vaccine that appears protective in young animals is much less protective, and potentially pathogenic, in an aged-animal model…

In each of the experiments conducted here, immunization with the whole inactivated SARS vaccine induced increased inflammatory infiltrates and pulmonary eosinophilia upon subsequent challenge, demonstrating the potential for dangerous clinical complications. This is consistent with two prior studies of vaccine formulations incorporating SARS N, where N-specific immune responses resulted in enhanced eosinophilic immune pathology. This pathological signature is reminiscent of the two known human examples of vaccine-induced immunopathology, atypical measles and enhanced RSV. For both of these vaccine-induced immunopathologies, infection subsequent to vaccination resulted in failure to control viral replication, enhanced clinical disease, and a pathology characterized by increased complement deposition and inflammation, skewing toward Th2 responses, and eosinophilic influx…

The major conclusion that can be drawn from these studies is that although DIV SARS vaccines do elicit protection under optimal conditions (homologous challenge in immunocompetent individuals), more stringent challenges reveal likely failures. If DIV vaccine approaches are to be used for SARS in the future, efforts must be made to improve the quality and magnitude of the vaccine-induced immune response while limiting the vaccine's capacity to induce immune pathology."

[690] ***Anti-Severe Acute Respiratory Syndrome Coronavirus Spike Antibodies Trigger Infection of Human Immune Cells via a pH- and Cysteine Protease-Independent FcγR Pathway***
Journal of Virology
Martial Jaume, Ming S. Yip, *et al*.
October 2011
https://journals.asm.org/doi/10.1128/JVI.00671-11

"**Abstract**: Public health measures successfully contained outbreaks of the severe acute respiratory syndrome coronavirus (SARS-CoV) infection. However, the precursor of the SARS-CoV remains in its natural bat reservoir, and reemergence of a human-adapted SARS-like coronavirus remains a plausible public health concern. Vaccination is a major strategy for containing resurgence of SARS in humans, and a number of vaccine candidates have been tested in experimental animal models. We previously reported that antibody elicited by a SARS-CoV vaccine candidate based on recombinant full-length Spike-protein trimers potentiated infection of human B cell lines despite eliciting *in vivo* a neutralizing and protective immune response in rodents. These observations prompted us to investigate the mechanisms underlying antibody-dependent enhancement (ADE) of SARS-CoV infection *in vitro*. We demonstrate here that anti-Spike immune serum, while inhibiting viral entry in a permissive cell line, potentiated infection of immune cells by SARS-CoV Spike-pseudotyped lentiviral particles, as well as replication-competent SARS coronavirus. Antibody-mediated infection was dependent on Fcγ receptor II but did not use the endosomal/lysosomal pathway utilized by angiotensin I converting enzyme 2 (ACE2), the accepted receptor for SARS-CoV. This suggests that **ADE of SARS-CoV utilizes a novel cell entry mechanism into immune cells**. Different SARS vaccine candidates elicit sera that differ in their capacity to induce ADE in immune cells despite their comparable potency to neutralize infection in ACE2-bearing cells. **Our results** suggest a novel mechanism by which SARS-CoV can enter target cells and **illustrate the potential pitfalls associated with immunization against it** [*emphasis added*]. These findings should prompt further investigations into SARS pathogenesis."

[691] **ADDED since 2/8/2022**
Antibody-mediated enhancement of disease in feline infectious peritonitis: Comparisons with dengue hemorrhagic fever
Comparative Immunology, Microbiology and Infectious Diseases — Cornell University
Richard C. Weiss and Fredric. W. Scott
1981
https://www.sciencedirect.com/science/article/pii/0147957181900035

"**Abstract**: Non-immune kittens passively immunized with feline serum containing high-titered antibodies reactive with feline infectious peritonitis virus (FIPV) developed a more rapid disease after FIPV challenge than did kittens pretreated with FIPV antibody-negative serum. Antibody-sensitized, FIPV challenged—kittens developed earlier clinical signs (including pyrexia, icterus, and thrombocytopenia) and died more rapidly than did non-sensitized, FIPV-challenged kittens. Mean survival time in sensitized kittens was significantly ($P < 0.05$) reduced compared to non-sensitized kittens (mean ± SEM, 10.0 ± 0.6 days vs. 28.8 ± 8.3 days, respectively). Lesions induced included fibrinous peritonitis, disseminated pyogranulomatous inflammation and necrotizing phlebitis and periphlebitis. FIPV antigen, immunoglobulin G, complement (C3) and fibrinogen were demonstrated in lesions by immunofluorescence microscopy.

The pathogenesis of dengue hemorrhagic fever (DHF) in persons bears striking resemblance to that of FIP in experimental kittens. In both FIP and DHF, **non-neutralizing antibody may promote acute disease** by enhancement of virus infection in mononuclear phagocytes or by formation of immune complexes, activation of complement and secondary vascular disturbances."

Vaccine (or Viral) Immune Escape (VIE)

[692] ***Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens***
PLOS Biology
Andrew F. Read, Susan J. Baigent, *et al*.
July 27, 2015
https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002198

"**Author Summary**: There is a theoretical expectation that some types of vaccines could prompt the evolution of more virulent ('hotter') pathogens. This idea follows from the notion that natural selection removes pathogen strains that are so 'hot' that they kill their hosts and, therefore, themselves. Vaccines that let the hosts survive but do not prevent the spread of the pathogen relax this selection, allowing the evolution of hotter pathogens to occur. This type of vaccine is often called a leaky vaccine. When vaccines prevent transmission, as is the case for nearly all vaccines used in humans, this type of evolution towards increased virulence is blocked. But when vaccines leak, allowing at least some pathogen transmission, **they could create the ecological conditions that would allow hot strains to emerge and persist** [*emphasis added*]. This theory proved highly controversial when it was first proposed over a decade ago, but here we report experiments with Marek's disease virus in poultry that show that modern commercial leaky vaccines can have precisely this effect: they allow the onward transmission of strains otherwise too lethal to persist. Thus, the use of leaky vaccines can facilitate the evolution of pathogen strains that put unvaccinated hosts at greater risk of severe disease…

Introduction: Infectious agents can rapidly evolve in response to health interventions [1]. Here, we ask whether pathogen adaptation to vaccinated hosts can result in the evolution of more virulent pathogens (defined here to mean those that cause more or faster mortality in unvaccinated hosts).

Vaccination could prompt the evolution of more virulent pathogens in the following way. It is usually assumed that the primary force preventing the evolutionary emergence of more virulent strains is that they kill their hosts and, therefore, truncate their own infectious periods. If so, keeping hosts alive with vaccines that reduce disease but do not prevent infection, replication, and transmission (so-called "imperfect" vaccines) could allow more virulent strains to circulate. Natural selection will even favour their circulation if virulent strains have a higher transmission in the absence of host death or are better able to overcome host immunity. Thus, life-saving **vaccines have the potential to increase mean disease virulence** of a pathogen population (as assayed in unvaccinated hosts)."

[693] **ADDED since 2/8/2022**

Vaccines Are Pushing Pathogens to Evolve

Quanta Magazine
Melinda Wenner Mayer
May 10, 2018
https://www.quantamagazine.org/vaccines-are-pushing-pathogens-to-evolve-20180510

> "Just as antibiotics breed resistance in bacteria, vaccines can incite changes that enable diseases to escape their control. Researchers are working to head off the evolution of new threats…
>
> Evolutionary biologists aren't surprised that this is happening. A vaccine is a novel selection pressure placed on a pathogen, and if the vaccine does not eradicate its target completely, then the remaining pathogens with the greatest fitness — those able to survive, somehow, in an immunized world — will **become more common**. 'If you don't have these pathogens evolving in response to vaccines,' said Paul Ewald, an evolutionary biologist at the University of Louisville, 'then we really don't understand natural selection.'…
>
> Vaccine science is brow-furrowingly complicated, but the underlying mechanism is simple. A vaccine exposes your body to either live but weakened or killed pathogens, or even just to certain bits of them. This exposure incites your immune system to create armies of immune cells, some of which secrete antibody proteins to recognize and fight off the pathogens if they ever invade again.
>
> That said, many vaccines don't provide lifelong immunity, for a variety of reasons. A new flu vaccine is developed every year because influenza viruses naturally mutate quickly. Vaccine-induced immunity can also wane over time. After being inoculated with the shot for typhoid, for instance, a person's levels of protective antibodies drop over several years, which is why public health agencies recommend regular boosters for those living in or visiting regions where typhoid is endemic. Research suggests a similar drop in protection over time occurs with the mumps vaccine, too.
>
> Vaccine failures caused by vaccine-induced evolution are different. These drops in vaccine effectiveness are incited by changes in pathogen populations that t**he vaccines themselves directly cause**. Scientists have recently started studying the phenomenon in part because they finally can: Advances in genetic sequencing have made it easier to see how microbes change over time. And many such findings have reinforced just how quickly pathogens mutate and evolve in response to environmental cues…
>
> Vaccines should also bar pathogens from replicating and transmitting inside inoculated hosts. One of the reasons that vaccine resistance is less of a problem than antibiotic resistance, Read and Kennedy posit, is that antibiotics tend to be given after an infection has already taken hold — when the pathogen population inside the host is already large and genetically diverse and might include mutants that can resist the drug's effects. Most vaccines, on the other hand, are administered before infection and limit replication, which minimizes evolutionary opportunities."

Note: The citations below are presented in reverse, chronological order.

[694] **ADDED since 2/8/2022**
Are Vaccines Fueling New Covid Variants?
Wall Street Journal
Allysia Finley
January 1, 2023
https://www.wsj.com/articles/are-vaccines-fueling-new-covid-variants-xbb-northeast-antibodies-mutation-strain-immune-imprinting-11672483618

> "Public-health experts are sounding the alarm about a new Omicron variant dubbed XBB that is rapidly spreading across the Northeast U.S.
>
> Some studies suggest it is as different from the original COVID strain from Wuhan as the 2003 SARS virus… It isn't clear that XBB is any more lethal than other variants, but its mutations enable it to evade antibodies from prior infection and vaccines as well as existing monoclonal antibody treatments.
>
> Growing evidence also suggests that repeated vaccinations may make people more susceptible to XBB and could be fueling the virus's rapid evolution…
>
> Under selective evolutionary pressures, the virus appears to have developed mutations that enable it to transmit more easily and escape antibodies elicited by vaccines and prior infection.
>
> The same study posits that immune imprinting may be contributing to the viral evolution. Vaccines do a good job of training the immune system to remember and knock out the original Wuhan variant. But when new and markedly different strains come along, the immune system responds less effectively."

[695] **ADDED since 2/8/2022**
Comparative analysis of within-host diversity among vaccinated COVID-19 patients infected with different SARS-CoV-2 variants
iScience — Qatar University
Hebah A. Al-Khatib, Maria K. Smatti, *et al*.
October 24, 2022
https://www.cell.com/iscience/fulltext/S2589-0042(22)01710-2

> "**Summary**: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a rapidly evolving RNA virus that mutates within hosts and exists as viral quasispecies. Here, we evaluated the within-host diversity among vaccinated and unvaccinated individuals (n = 379) infected with different SARS-CoV-2 Variants of Concern. The majority of samples harbored less than 14 intra-host single-nucleotide variants (iSNVs). A deep analysis revealed a significantly higher intra-host diversity in Omicron samples than in other variants (p value < 0.05). Vaccination status and type had a limited impact on intra-host diversity **except for Beta-B.1.315 and Delta-B.1.617.2 vaccinees, who exhibited higher diversity than unvaccinated individuals** (p values: <0.0001 and <0.0021, respectively). Three immune-escape mutations were identified: S255F in Delta and R346K and T376A in Omicron-B.1.1.529. The latter 2 mutations were fixed in BA.1 and BA.2 genomes, respectively. Overall, the relatively higher intra-host diversity among vaccinated individuals and the detection of immune-escape mutations, despite being rare, suggest a potential vaccine-induced immune

pressure in vaccinated individuals."

[696] **ADDED since 2/8/2022**
Emerging Vaccine-Breakthrough SARS-CoV-2 Variants
ACS Infectious Diseases — Michigan State University
Rui Wang, Jiahui Chen, Yuta Hozumi, Changchuan Yin, and Guo-Wei Wei
February 8, 2022
https://pubs.acs.org/doi/10.1021/acsinfecdis.1c00557

"**Abstract**: The surge of COVID-19 infections has been fueled by new SARS-CoV-2 variants, namely Alpha, Beta, Gamma, Delta, and so forth. The molecular mechanism underlying such surge is elusive due to the existence of 28 554 unique mutations, including 4 653 non-degenerate mutations on the spike protein. Understanding the molecular mechanism of SARS-CoV-2 transmission and evolution is a prerequisite to foresee the trend of emerging vaccine-breakthrough variants and the design of mutation-proof vaccines and monoclonal antibodies. We integrate the genotyping of 1 489 884 SARS-CoV-2 genomes, a library of 130 human antibodies, tens of thousands of mutational data, topological data analysis, and deep learning to reveal SARS-CoV-2 evolution mechanism and forecast emerging vaccine-breakthrough variants. We show that prevailing variants can be quantitatively explained by infectivity-strengthening and **vaccine-escape (co-)mutations on the spike protein RBD due to natural selection and/or vaccination-induced evolutionary pressure**. We illustrate that infectivity strengthening mutations were the main mechanism for viral evolution, while vaccine-escape mutations become a dominating viral evolutionary mechanism among highly vaccinated populations. We demonstrate that Lambda is as infectious as Delta but is more vaccine-resistant. We analyze emerging vaccine-breakthrough comutations in highly vaccinated countries, including the United Kingdom, the United States, Denmark, and so forth. Finally, we identify sets of **comutations that have a high likelihood of massive growth**: [A411S, L452R, T478K], [L452R, T478K, N501Y], [V401L, L452R, T478K], [K417N, L452R, T478K], [L452R, T478K, E484K, N501Y], and [P384L, K417N, E484K, N501Y]. We predict they can escape existing vaccines. We foresee an **urgent need to develop new virus combating strategies**."

[697] ***Mechanisms of SARS-CoV-2 Evolution Revealing Vaccine-Resistant Mutations in Europe and America***
Journal of Physical Chemistry Letters (Michigan State University)
Rui Wang, Jiahui Chen, and Guo-Wei Wei
December 7, 2021
https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8672435/

"**Abstract**: The importance of understanding SARS-CoV-2 evolution cannot be overlooked. Recent studies confirm that natural selection is the dominating mechanism of SARS-CoV-2 evolution, which favors mutations that strengthen viral infectivity. Here, we demonstrate that vaccine-breakthrough or antibody-resistant mutations provide a new mechanism of viral evolution. Specifically, vaccine-resistant mutation Y449S in the spike (S) protein receptor-binding domain, which occurred in co-mutations Y449S and N501Y, has reduced infectivity compared to that of the original SARS-CoV-2 but can disrupt existing antibodies that neutralize the virus. By tracking the evolutionary trajectories of vaccine-resistant mutations in more than 2.2 million SARS-CoV-2 genomes, we reveal that **the occurrence** and **frequency**

of vaccine-resistant mutations correlate strongly with the vaccination rates in Europe and America [*emphasis added*]. We anticipate that as a complementary transmission pathway, vaccine-breakthrough or antibody-resistant mutations, like those in Omicron, will become a dominating mechanism of SARS-CoV-2 evolution when most of the world's population is either vaccinated or infected."

[698] ***Continued mass vaccination will only push the evolutionary capacity of SARS-CoV-2 Spike protein beyond the Omicron version***
Dr. Geert Vanden Bossche, former Senior Program Officer with the Bill & Melinda Gates Foundation, former Senior Ebola Program Manager at the Global Alliance for Vaccines and Immunization (GAVI)
November 30, 2021
https://www.voiceforscienceandsolidarity.org/scientific-blog/mass-vaccination-will-push-sars-cov-2-spike-protein-beyond-omicron

"Scientific naivete combined with arrogant megalomania has led the mighty alliance of PH-KOL and Industry to dramatically underestimate the evolutionary capacity of SARS-CoV-2 when it is put under widespread immune pressure. There can be no doubt that Omicron is only one such example of this and that other variants harboring a similar panoply of S-directed mutations will soon emerge in other countries. There is, indeed, no reason to believe that identical conditions of suboptimal population-level immune pressure on SARS-CoV-2 infectiousness combined with widespread infectious pressure would lead to different results. Alternatively, countries which – thanks to mass vaccination – have prepared their populations to serve as an excellent breeding ground for more infectious variants will exhibit a high level of hospitality to Omicron and its peers…

Mass vaccination promotes viral resistance to C-19 vaccines. Viral resistance drives enhanced infectiousness of SARS-CoV-2 (e.g., Omicron) and **may ultimately enable SARS-CoV-2 to utilize alternative cell surface determinants to enter permissive cells**…

It is undeniable that mass vaccination will only drive the virus to fully exploit its evolutionary capacity, including – if needed – its ability to use alternate receptor domains on permissive cells. The fitness cost that may come with such a dramatic mutation is likely to be rewarded with enhanced pathogenicity. I am truly afraid that these dynamics will eventually allow for the natural selection of individuals with uncompromised innate immunity while **eliminating those without it** [*emphasis added*]. While such natural selection would lead to an eradication of SARS-CoV-2 as innate immunity sterilizes the virus and blocks transmission, the consequences would be unimaginable – the price paid for ending the pandemic by virus eradication is not comparable to the one paid for by generating herd immunity and allowing the virus to enter an endemic state. Those who are enforcing mass vaccination are opting for the former instead of the latter, an act that will be remembered as the deadliest sin ever."

[699] ***The spike protein of SARS-CoV-2 variant A.30 is heavily mutated and evades vaccine-induced antibodies with high efficiency***
Cellular & Molecular Immunology (Nature)
Prerna Arora, Cheila Rocha, *et al*.
October 25, 2021
https://www.nature.com/articles/s41423-021-00779-5

> "In summary, A.30 exhibits a cell line preference not observed for other viral variants and efficiently evades neutralization by antibodies elicited by ChAdOx1 nCoV-19 [*Astrazeneca*] or BNT162b2 vaccination [*Pfizer*]… Notably, **robust entry into cell lines** was combined with **high resistance against antibodies** induced upon ChAdOx1 nCoV-19 or BNT162b2 vaccination [*emphasis added*]... Collectively, our results suggest that the SARS-CoV-2 variant A.30 can evade control by vaccine-induced antibodies and might show an increased capacity to enter cells in a cathepsin L-dependent manner, which might particularly aid in the extrapulmonary spread. As a consequence, the potential spread of the A.30 variant warrants close monitoring."

[700] **Virtual meeting (video): *Vaccines and Related Biological Products Advisory Committee*, *remarks by Dr. Jessica Rose***
Food and Drug Administration (FDA)
September 17, 2021
https://youtu.be/WFph7-6t34M?t=14985

> **Rose (starting at 4:09:45)**: "Israel's one of the most injected countries, and it appears from this data that this represents a clear failure of these products to provide protective immunity against emerging variants and to prevent transmission, regardless of how many additional shots administered.
>
> And this begs the question as to whether **these injection rollouts are driving the emergence of the new variants**. There's a clear and present danger of the emergence of variants of concern if we continue with these alleged booster shots [*emphasis added*]."

[701] ***Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California***
University of California, San Francisco
Venice Servellita, Mary-Kate Morris, *et al*.
August 25, 2021
https://www.medrxiv.org/content/10.1101/2021.08.19.21262139v1.full-text

> "**Abstract**: Associations between vaccine breakthrough cases and infection by SARS coronavirus 2 (SARS-CoV-2) variants have remained largely unexplored. Here we analyzed SARS-CoV-2 whole-genome sequences and viral loads from 1,373 persons with COVID-19 from the San Francisco Bay Area from February 1 to June 30, 2021, of which 125 (9.1%) were vaccine breakthrough infections. Fully vaccinated were more likely than unvaccinated persons to be infected by variants carrying mutations associated with decreased antibody neutralization (L452R, L452Q, E484K, and/or F490S) (78% versus 48%, p = 1.96e-08), but not by those associated with increased infectivity (L452R and/or N501Y) (85% versus 77%, p = 0.092). Differences in viral loads were non-significant between unvaccinated and fully vaccinated persons overall (p = 0.99) and according to lineage (p = 0.09 – 0.78)… In 5 cases

with available longitudinal samples for serologic analyses, vaccine breakthrough infections were found to be associated with **low or undetectable neutralizing antibody levels** attributable to immunocompromised state or infection by an antibody-resistant lineage [*emphasis added*]. These findings suggest that vaccine breakthrough cases are preferentially caused by circulating antibody-resistant SARS-CoV-2 variants, and that symptomatic breakthrough infections may potentially transmit COVID-19 as efficiently as unvaccinated infections, regardless of the infecting lineage…

Discussion: … [W]e found that vaccine breakthrough infections are more likely to be caused by immunity-evading variants as compared to unvaccinated infections. These findings are largely attributed to the observed decreased proportion of vaccine breakthrough infections from the alpha variant, despite its documented higher infectivity relative to all VOCs except delta and gamma. Decreased alpha infections are consistent with the higher effectiveness of available SARS-CoV-2 vaccines against alpha relative to other VOCs, most of which exhibit higher resistance to neutralizing antibodies than alpha. **The predominance of immune-evading variants among breakthrough cases indicates selective pressure for immune-resistant variants** locally over time in the vaccinated population concurrent with ongoing viral circulation in the community [*emphasis added*]. In particular, the delta variant, which is the predominant circulating lineage in the United States as of July 2021, has been shown to be resistant to vaccine-induced immunity as well as being more infectious than alpha"

[702] ***The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines***
Osaka University (Japan)
Yafei Liu, Noriko Arase, *et al*.
August 23, 2021
https://www.biorxiv.org/content/10.1101/2021.08.22.457114v1.full

"**Discussion**: … SARS-CoV-2 has acquired a number of mutations to date, which have arisen within infected individuals. Therefore, new variants are likely to emerge more frequently in situations where many people are infected. Because the Delta variant is spreading so explosively, it has already acquired numerous additional mutations in the spike protein coding region, suggesting that the Delta variant will continue to acquire further mutations. Some mutations observed in the RBD [*receptor binding domain*] of the Delta variant have been reported to be epitopes for anti-RBD neutralizing antibodies (Greaney et al., 2021a; Greaney et al., 2021b; Wang et al., 2021b). **Newly emerged variants** that adapt to the environment of their host's immune system **will be selected** and **expand**. The Delta variant with 4 additional mutations in the RBD were not neutralized by most BNT162b2-immune sera because of unique mutations in the NTD. More importantly, **infectivity of the Delta 4+ was enhanced** by some BNT162b2-immune sera [*emphasis added*]. Furthermore, of the four additional mutations, a Delta variant with three mutations has already been registered in the GISAID database; it is likely that a Delta variant that has acquired five mutations in the RBD in total will acquire additional mutations in the near future. Although we have selected K417N, N439K, E484K, and N501Y as additional mutations for the Delta variant, **other combinations** of anti-RBD neutralizing epitopes can be expected to have similar or **stronger effects** than the Delta 4+ variant [*emphasis added*]. Indeed, the Delta 4+ still possess R346, one of major epitope residues for anti-RBD neutralizing antibodies such as C135...

A third round of booster immunization with the SARS-CoV-2 vaccine is currently under consideration. Our data suggest that repeated immunization with the wild-type spike may not be effective in controlling the newly emerging Delta variants."

[703] **Video (2m): Interview excerpt with Luc Montagnier (2008 Nobel Prize in Medicine)**
August 18, 2021
https://rumble.com/vldilx-nobel-prize-winner-professor-luc-montagnier-says-vaccine-is-creating-varian.html

"[I]t is the vaccinations that are causing the variants… The **new variants are a production and result from the vaccination** [*emphasis added*]… You see it in each country, it's the same: The curve of vaccination is followed by the curve of deaths… I'm following this closely and I am doing experiments at the institute with patients who become sick with Corona after being vaccinated. I will show you that they are creating the variants that are resistant to the vaccine."

[704] ***The emergence and ongoing convergent evolution of the N501Y lineages coincides with a major global shift in the SARS-CoV-2 selective landscape***
University of Cape Town (South Africa)
Darren P. Martin, Steven Weaver, *et al*.
July 25, 2021
https://www.medrxiv.org/content/10.1101/2021.02.23.21252268v3.full-text

"**Abstract**: The emergence and rapid rise in prevalence of three independent SARS-CoV-2 "501Y lineages", B.1.1.7, B.1.351 and P.1, in the last three months of 2020 prompted **renewed concerns about the evolutionary capacity of SARS-CoV-2 to adapt to** both rising population immunity, and **public health interventions such as vaccines** and social distancing. Viruses giving rise to the different 501Y lineages have, presumably under intense natural selection following a shift in host environment, independently acquired multiple unique and convergent mutations. As a consequence, **all have gained epidemiological and immunological properties that will likely complicate the control of COVID-19** [*emphasis added*]. Here, by examining patterns of mutations that arose in SARS-CoV-2 genomes during the pandemic we find evidence of a major change in the selective forces acting on various SARS-CoV-2 genes and gene segments (such as S, nsp2 and nsp6), that likely coincided with the emergence of the 501Y lineages. In addition to involving continuing sequence diversification, we find evidence that a significant portion of the ongoing adaptive evolution of the 501Y lineages also involves further convergence between the lineages. Our findings highlight the importance of monitoring how members of these known 501Y lineages, and others still undiscovered, are convergently evolving similar strategies to ensure their persistence in the face of mounting infection and vaccine induced host immune recognition."

[705] ***Ninety-third SAGE meeting on COVID-19***
Scientific Advisory Group for Emergencies (SAGE)
July 7, 2021
https://www.gov.uk/government/publications/sage-93-minutes-coronavirus-covid-19-response-7-july-2021/sage-93-minutes-coronavirus-covid-19-response-7-july-2021

> "9. There are four major risks associated with high numbers of infections. These are an increase in hospitalisations and deaths, more 'Long-COVID'; workforce absences (including in the NHS); and the increased risk of new variants emerging. The combination of high prevalence and high levels of vaccination **creates the conditions in which an immune escape variant is most likely to emerge** [*emphasis added*]. The likelihood of this happening is unknown, but such a variant would present a significant risk both in the UK and internationally."

[706] ***Antigenic minimalism of SARS-CoV-2 is linked to surges in COVID-19 community transmission and vaccine breakthrough infections***
Mayo Clinic
A.J. Venkatakrishnan, Praveen Anand, *et al*.
May 31, 2021
https://www.medrxiv.org/content/10.1101/2021.05.23.21257668v1.full-text

> "**Abstract**: The raging COVID-19 pandemic in India and reports of 'vaccine breakthrough infections' globally have raised alarm mandating the characterization of the immuno-evasive features of SARS-CoV-2. Here, we systematically analyzed over 1.3 million SARS-CoV-2 genomes from 178 countries and performed whole-genome viral sequencing from 53 COVID-19 patients, including 20 vaccine breakthrough infections. We identified 116 Spike protein mutations that increased in prevalence during at least one surge in SARS-CoV-2 test positivity in any country over a three-month window. Deletions in the Spike protein N-terminal domain (NTD) are highly enriched for these 'surge-associated mutations'… Overall, the expanding repertoire of NTD deletions throughout the pandemic and their association with case surges and vaccine breakthrough infections point to antigenic minimalism as an emerging evolutionary strategy for SARS-CoV-2 to evade immune responses. This study highlights the urgent need to sequence viral genomes at a larger scale globally and to mandate that sequences are deposited with more granular and transparent clinical annotations to ensure that therapeutic development keeps pace with the evolution of SARS-CoV-2.
>
> **Introduction**: The ongoing COVID-19 pandemic has infected around 160 million people and killed more than 3 million people worldwide, as of May 20211. The **continual emergence of SARS-CoV-2 variants** with increased transmissibility and **capacity for immune escape**, such as B.1.1.7 ('UK variant') and P.1 ('Brazilian variant'), threatens to prolong the pandemic through **devastating outbreaks** such as the one currently being witnessed in India [*emphasis added*]…
>
> **Results**: … This suggests that the surging SARS-CoV-2 variants in India and Chile may have acquired NTD deletions in the antigenic supersite in order to evade neutralizing antibodies and achieve immune escape. From a viral evolution standpoint, these observations raise the question of whether SARS-CoV-2 is expanding its repertoire of deletable regions in the Spike protein as the pandemic progresses.

Discussion: The worldwide mass vaccination campaign has had a profound impact on COVID-19 transmission. However, certain variants are less susceptible to neutralization by sera from vaccinated individuals and convalescent COVID-19 patients. Such findings motivate the need to vigilantly track the emergence of new variants and to determine whether they are likely to cause surges or vaccine breakthrough infections… Thus, a concerted evolution of strategically placed deletions and substitutions appear to be conferring SARS-CoV-2 with the fitness to evade immunity and achieve efficient transmission between hosts."

[707] ***SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety that demand answers from international health agencies, regulatory authorities, governments and vaccine developers***
Roxana Bruno, Peter A. Mccullough, *et al*.
May 2021
https://www.researchgate.net/publication/351670290_SARS-CoV-2_mass_vaccination_Urgent_questions_on_vaccine_safety_that_demand_answers_from_international_health_agencies_regulatory_authorities_governments_and_vaccine_developers

See [388]

[708] ***Risk of rapid evolutionary escape from biomedical interventions targeting SARS-CoV-2 spike protein***
PLOS One (Harvard Medical School, Massachusetts Institute of Technology, and Boston Children's Hospital)
Debra van Egeren, Alexander Novokhodko, *et al*.
April 28, 2021
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0250780

"**Abstract**: The spike protein receptor-binding domain (RBD) of SARS-CoV-2 is the molecular target for many vaccines and antibody-based prophylactics aimed at bringing COVID-19 under control. Such a narrow molecular focus **raises the specter of viral immune evasion as a potential failure mode for these biomedical interventions** [*emphasis added*]. With the emergence of new strains of SARS-CoV-2 with altered transmissibility and immune evasion potential, a critical question is this: how easily can the virus escape neutralizing antibodies (nAbs) targeting the spike RBD? To answer this question, we combined an analysis of the RBD structure-function with an evolutionary modeling framework. Our structure-function analysis revealed that epitopes for RBD-targeting nAbs overlap one another substantially and can be evaded by escape mutants with ACE2 affinities comparable to the wild type, that are observed in sequence surveillance data and infect cells in vitro. This suggests that the fitness cost of nAb-evading mutations is low. We then used evolutionary modeling to predict the frequency of immune escape before and after the widespread presence of nAbs due to vaccines, passive immunization or natural immunity. Our modeling suggests that SARS-CoV-2 mutants with one or two mildly deleterious mutations are expected to exist in high numbers due to neutral genetic variation, and consequently **resistance to vaccines or other prophylactics that rely on one or two antibodies for protection can develop quickly - and repeatedly- under positive selection** [*emphasis added*]. Predicted resistance timelines are comparable to those of the decay kinetics of nAbs raised against vaccinal or natural antigens, raising a second potential mechanism for loss of immunity in the population. Strategies for viral elimination should therefore be diversified across molecular targets and therapeutic modalities…

Introduction: … [T]he evolutionary rate prior to the widespread deployment of vaccines or development of natural immunity (based primarily on neutral genetic drift) may underestimate the evolutionary potential of the virus to evade nAbs deployed as active immunity (vaccines) or passive immunity (nAb prophylactics). When nAbs are broadly present in the population, population-level selection for antibody-evading, infection-competent viral mutants may result in a rapid resurgence of SARS-CoV-2 infections…

Discussion: … Evidence from multiple experimental studies … suggests that **specific single mutants may be able to evade spike-targeting vaccinal immunity in many individuals and rapidly lead to spread of vaccine-resistant SARS-CoV-2** [*emphasis added*]. One variant that can escape convalescent plasma neutralization is already circulating in South Africa and could experience greater positive selection pressure once vaccines are deployed widely…

Finally, the overall size of the pandemic in terms of number of active infections will play a significant role in whether the virus can be brought under control with nAb prophylactics or vaccines. The speed at which nAb resistance develops in the population increases substantially as the number of infected individuals increases, suggesting that complementary strategies to prevent SARS-CoV-2 transmission that exert specific pressure on other proteins (e.g., antiviral prophylactics) or that do not exert a specific selective pressure on the virus (e.g., high-efficiency air filtration, masking, ultraviolet air purification) are key to reducing the risk of immune escape. In this context, **vaccines that do not provide sterilizing immunity** (and therefore continue to permit transmission) **will lead to the buildup** of large standing populations **of virus, greatly increasing the risk of immune escape** [*emphasis added*]."

[709] **Open Letter to the World Health Organization**
Dr. Geert Vanden Bossche, DVM, PhD
March 6, 2021
https://37b32f5a-6ed9-4d6d-b3e1-5ec648ad9ed9.filesusr.com/ugd/28d8fe_266039aeb27a4465988c37adec9cd1dc.pdf

"I am all but an antivaxxer. As a scientist, I do not usually appeal to any platform of this kind to make a stand on vaccine-related topics. As a dedicated virologist and vaccine expert, I only make an exception when health authorities allow vaccines to be administered in ways that threaten public health, most certainly when scientific evidence is being ignored. The present extremely critical situation forces me to spread this emergency call. As the unprecedented extent of human intervention in the Covid-19-pandemic is now at risk of resulting in a global catastrophe without equal, this call cannot sound loudly and strongly enough."

Video (2m): Urgent call to WHO: Time to switch gears
https://www.youtube.com/watch?v=mUlDeCRDLnU

[710] ***Will Delaying Vaccine Doses Cause a Coronavirus Escape Mutant?***
The Scientist
Chris Baraniuk
February 4, 2021
https://www.the-scientist.com/news-opinion/will-delaying-vaccine-doses-cause-a-coronavirus-escape-mutant--68424

> "Among those concerned is Paul Bieniasz, a virologist at the Rockefeller University. 'Rolling out a partially effective vaccine regime in the peak of a highly prevalent viral epidemic is just not a great idea if one of your goals is to avoid vaccine resistance,' he says.
>
> There's a chance, Bieniasz explains, that people waiting for their second dose may have a sub-optimal level of immunity that places selective pressure on the virus. If someone were to become infected during the interval between jabs, that pressure could allow for the emergence of a mutant version of SARS-CoV-2 able to shake off a person's immune response—a so-called escape variant. Any such variant that also proved capable of causing severe disease could potentially spark a **whole new, devastating wave of infections and deaths**."

Known and Potential Consequences of COVID-19 Vaccinations

Overview

See also:

- Credentialed Opposition to further Distribution of COVID-19 Vaccines
- Personal Testimonials and Documentaries on Vaccine Injuries

[711] ***VAERS COVID Vaccine Data***
OpenVAERS
Total numbers for adverse events reported to VAERS by category (e.g., anaphylaxis, Bell's palsy, Guillain-Barré syndrome, thrombocytopenia, etc.).
https://www.openvaers.com/covid-data

[712] **ADDED since 2/8/2022**
Peer Reviewed Medical Papers Submitted To Various Medical Journals, Evidencing A Multitude Of Adverse Events In Covid-19 Vaccine Recipients
COVID Medical Network
https://www.covidmedicalnetwork.com/coronavirus-facts/vaccine/4_590246584570295411 2.pdf
"We are a group of senior medical doctors and health professionals concerned about the health impacts of the lockdowns used in response to the SARS-CoV-2 outbreaks across Australia."

"A comprehensive list of resource materials on Covid-19 vaccine adverse events."

[713] ***Case Series Drug Analysis Print - COVID-19 mRNA Pfizer- BioNTech vaccine analysis print***
Medicines and Healthcare products Regulatory Agency
Report Run Date: August 26, 2021
Total numbers for adverse events reported to the United Kingdom's 'Yellow-Card System" for the Pfizer vaccine (tabulated by category).
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012207/COVID-19_mRNA_Pfizer-_BioNTech_vaccine_analysis_print_final.pdf

[714] **Video (2h38m): Press conference - *Cause of Death after COVID-19 Vaccination and Undeclared Components of the COVID-19 Vaccines***
Pathological Institute (Reutlingen, Germany)
September 20, 2021
https://pathologie-konferenz.de/en/

[715] **ADDED since 2/8/2022**
Compilation: Peer Reviewed Medical Papers of COVID Vaccine Injuries — More than 1,000 Peer Reviewed Articles on COVID Vaccine Injuries
February 20, 2022
https://community.covidvaccineinjuries.com/compilation-peer-reviewed-medical-papers-of-covid-vaccine-injuries/

[716] **ADDED since 2/8/2022**
1000 Peer Reviewed Studies Questioning Covid-19 Vaccine Safety
Informed Choice Australia
January 19, 2022
https://www.informedchoiceaustralia.com/post/1000-peer-reviewed-studies-questioning-covid-19-vaccine-safety
Note: Categories include Myocarditis, Thrombosis, Thrombocytopenia, Cerebral Venous Thrombosis, Vasculitis, Guillain-Barré syndrome, Lymphadenopathy, Anaphylaxis, Myopericarditis, Allergic Reactions, Bell's Palsy, and more.

[717] **ADDED since 2/8/2022**
FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZERBIONTECH COVID-19 VACCINE AND THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 6 MONTHS THROUGH 4 YEARS OF AGE
Pfizer, Inc.
Revised December 8, 2022
https://labeling.pfizer.com/ShowLabeling.aspx?id=17228

"**WHAT ARE THE RISKS OF THESE VACCINES?**

There is a remote chance that these vaccines could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination.

Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Pfizer-BioNTech COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. In most of these people, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, particularly during the 2 weeks after your child receives a dose of either vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart
- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported with these vaccines include:

- Severe allergic reactions
- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site pain/tenderness
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Injection site swelling
- Injection site redness
- Nausea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)
- Decreased appetite
- Diarrhea
- Vomiting
- Arm pain
- Fainting in association with injection of the vaccine
- Dizziness
- Irritability

These may not be all the possible side effects of these vaccines. Serious and unexpected side effects may occur. The possible side effects of these vaccines are still being studied."

[718] ***5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received through 28-FEB-2021***
Pfizer, Inc.
Approved on April 30, 2021
https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf
Note: This document was produced by the Food and Drug Administration (FDA) in response to a Freedom of Information Act (FOIA) request (see https://phmpt.org/wp-content/uploads/2021/10/001-Complaint-101021.pdf).

> "**1. Introductio**n: … This document provides an integrated analysis of the **cumulative post-authorization safety data**, including U.S. and foreign post-authorization adverse event reports **received through 28 February 2021**…
>
> **2. Methodology**: … Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the **large numbers of spontaneous adverse event reports received for the product**, the MAH [*marketing authorisation holder*] has prioritised the processing of serious cases… Pfizer has also taken a multiple actions to help alleviate the **large increase of adverse event reports** [*emphasis added*]. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately [*REDACTED*] additional full-time employees (FTEs). More are joining each month with an expected total of more than [*REDACTED*] additional resources by the end of June 2021…
>
> **3. Results, 3.1.1. General Overview**: It is estimated that approximately [*REDACTED*] doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.
>
> Cumulatively, through 28 February 2021, there was a total of **42,086 case reports** (25,379 medically confirmed and 16,707 non-medically confirmed) **containing 158,893 events** [*emphasis added*]. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693)."

Note: The citations below are presented in reverse, chronological order.

[719] **ADDED since 2/8/2022**
Serious harms of the COVID-19 vaccines: a systematic review
Institute of Scientific Freedom, Denmark
Peter C. Gøtzsche and Maryanne Demasi
March 22, 2023
https://www.medrxiv.org/content/10.1101/2022.12.06.22283145v2.full-text

"**Methods**: Systematic review of papers with data on serious adverse events (SAEs) associated with a COVID-19 vaccine.

Results: We included 18 systematic reviews, 14 randomised trials, and 34 other studies with a control group. Most studies were of poor quality. The most reliable one was a systematic review of regulatory data on the two pivotal randomised trials of the mRNA vaccines. It found significantly more SAEs of special interest with the vaccines than with placebo, and the excess risk was considerably larger than the benefit, measured as the risk of hospitalisation. The **adenovirus vector vaccines** increased the risk of venous thrombosis and thrombocytopenia, and the **mRNA-based vaccines** increased the risk of myocarditis, with a mortality of about 1-2 per 200 cases. We also found evidence of serious neurological harms, including Bell's palsy, Guillain-Barré syndrome, myasthenic disorder and stroke, which are

likely due to an autoimmune reaction, as has been suggested also for the HPV vaccines. **Severe harms**, i.e. those that prevent daily activities, **were hugely underreported in the randomised trials**. These harms were very common in studies of booster doses after a full vaccination and in a study of vaccination of previously infected people...

Discussion: Serious and severe harms of the COVID-19 vaccines have been ignored or downplayed, and sometimes been deliberately excluded by the study sponsors in high impact medical journals. This area needs further study. Authorities have recommended virtually everyone get vaccinated and receive booster doses. They fail to consider that **the balance between benefits and harms becomes negative in low-risk groups** such as children and people who have already acquired natural immunity."

[720] **ADDED since 2/8/2022**

Surveillance of COVID-19 vaccine safety among elderly persons aged 65 years and older

Vaccine — US Food and Drug Administration

Hui-Lee Wong, Ellen Tworkoski, *et al*.

December 1, 2022

https://www.sciencedirect.com/science/article/pii/S0264410X22014931

"**Background**: Monitoring safety outcomes following COVID-19 vaccination is critical for understanding vaccine safety especially when used in key populations such as elderly persons age 65 years and older who can benefit greatly from vaccination. We present new findings from a nationally representative early warning system that may expand the safety knowledge base to further public trust and inform decision making on vaccine safety by government agencies, healthcare providers, interested stakeholders, and the public...

Methods: We evaluated 14 outcomes of interest following COVID-19 vaccination using the US Centers for Medicare & Medicaid Services (CMS) data covering 30,712,101 elderly persons. The CMS data from December 11, 2020 through Jan 15, 2022 included 17,411,342 COVID-19 vaccinees who received a total of 34,639,937 doses…

Findings: Four outcomes met the threshold for a statistical signal following BNT162b2 vaccination including pulmonary embolism (PE; RR = 1.54), **acute myocardial infarction** (AMI; RR = 1.42), **disseminated intravascular coagulation** (DIC; RR = 1.91), and **immune thrombocytopenia** (ITP; RR = 1.44)...

Interpretation: … Because an early warning system does not prove that the vaccines cause these outcomes, more robust epidemiologic studies with adjustment for confounding, including age and nursing home residency, are underway to further evaluate these signals. FDA strongly believes the potential benefits of COVID-19 vaccination outweigh the potential risks of COVID-19 infection…

3.3. Signal evaluation: None of the prespecified data quality assurance checks, including claims duplication and unusual variability in claim accrual, raised data quality concerns (Table S9). Primary findings for signal robustness and signal characterization analyses are summarized in Table 3. Adjustment for monthly variation in the background rates resulted in statistically non-significant associations for AMI, DIC, and ITP following BNT162b2 vaccination. With background rates from the flu-vaccinated population as the historical comparator, DIC and ITP no longer met the signal threshold, while signals for **AMI** (RR = 1.41) and **PE** (RR = 1.48) remained [*acute myocardial infarction and pulmonary embolism*]. When rates during the

peri-COVID period were used as the historical comparator, PE and DIC no longer met the signal threshold. We conducted an additional ad hoc sensitivity analysis for PE. When PE events were restricted to the inpatient setting, the statistical signal remained (RR = 2.17)."

[721] **ADDED since 2/8/2022**

Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 1

Journal of Insulin Resistance
Aseem Molhotra, Cardiology MSc examiner at the University of Hertfordshire, UK
September 26, 2022
https://insulinresistance.org/index.php/jir/article/view/71/221

"**Background**: In response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), several new pharmaceutical agents have been administered to billions of people worldwide, including the young and healthy at little risk from the virus. Considerable leeway has been afforded in terms of the pre-clinical and clinical testing of these agents, despite an entirely novel mechanism of action and concerning biodistribution characteristics.

Aim: To gain a better understanding of the true benefits and potential harms of the messenger ribonucleic acid (mRNA) coronavirus disease (COVID) vaccines.

Methods: A narrative review of the evidence from randomised trials and real world data of the COVID mRNA products with special emphasis on BionTech/Pfizer vaccine.

Results: In the non-elderly population the **'number needed to treat' to prevent a single death runs into the thousands**. Re-analysis of randomised controlled trials using the messenger ribonucleic acid (mRNA) technology suggests a **greater risk of serious adverse events from the vaccines than being hospitalised from COVID-19**. Pharmacovigilance systems and real-world safety data, coupled with plausible mechanisms of harm, are deeply concerning, especially in relation to cardiovascular safety. Mirroring a potential signal from the Pfizer Phase 3 trial, a significant rise in cardiac arrest calls to ambulances in England was seen in 2021, with similar data emerging from Israel in the 16–39-year-old age group.

Conclusion: It cannot be said that the consent to receive these agents was fully informed, as is required ethically and legally. A pause and reappraisal of global vaccination policies for COVID-19 is long overdue."

[722] **ADDED since 2/8/2022**

Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials

Vaccine journal
Joseph Fraiman, Juan Erviti, *et al*.
September 22, 2022
https://www.sciencedirect.com/science/article/pii/S0264410X22010283

"**Introduction**: In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials.

Methods: Secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427), focusing analysis on Brighton Collaboration adverse events of special interest.

Results: Pfizer and Moderna mRNA COVID-19 vaccines were associated with an e**xcess risk of serious adverse events of special interest** of **10.1** and **15.1** per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95 % CI −0.4 to 20.6 and −3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an excess risk of serious adverse events of special interest of **12.5** per 10,000 vaccinated (95 % CI 2.1 to 22.9); risk ratio 1.43 (95 % CI 1.07 to 1.92). The Pfizer trial exhibited a 36 % higher risk of serious adverse events in the vaccine group; risk difference 18.0 per 10,000 vaccinated (95 % CI 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of serious adverse events in the vaccine group: risk difference 7.1 per 10,000 (95 % CI –23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of serious adverse events in mRNA vaccine recipients: risk difference 13.2 (95 % CI −3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39).

Discussion: The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets.

… These results raise concerns that mRNA vaccines are associated with more harm than initially estimated at the time of emergency authorization…

Rational policy formation should consider potential harms alongside potential benefits. To illustrate this need in the present context, we conducted a simple harm-benefit comparison using the trial data comparing excess risk of serious AESI against reductions in COVID-19 hospitalization. We found excess risk of serious AESIs **to exceed** the reduction in COVID-19 hospitalizations in both Pfizer and Moderna trials."

[723] **ADDED since 2/8/2022**
COVID-19 vaccines – An Australian Review
Journal of Clinical & Experimental Immunology
Conny Turni and Astrid Lefringhausen
September 21, 2022
https://canadahealthalliance.org/wp-content/uploads/2022/09/covid-19-vaccines-an-australian-review.pdf

"**Abstract**: After millions of people have been vaccinated as often as four times within a year, the effects of these vaccinations are slowly becoming apparent. This review has been written from an Australian perspective with the main focus on the COVID-19 mRNA vaccines. We will look at the promises/predictions originally made and the actual facts. We will evaluate the safety and efficacy by looking at the literature and the data from government agencies. The literature review will be summed up in a table listing the so far reported side effects of which many are very serious including death, with this data coming from 1011 case reports. Long term side effects will also be covered and the risk benefit ratio will be explored. The review is ending with some very critical question that need further discussion.

Introduction: … The official public message is that the mRNA vaccines are safe. However, the Therapeutic Goods Administration (TGA), the medicine and therapeutic regulatory agency of the Australian Government, states quite clearly on their website that **the large-scale trials are still progressing** and **no full data package has been received from any company**. The TGA is currently getting rolling data and safety and effectiveness are still being assessed (https://www.tga.gov.au/covid-19-vaccines-undergoingevaluation)...

Protection: … A worldwide Bayesian causal Impact analysis suggests that COVID-19 gene therapy (mRNA vaccine) **causes more COVID-19 cases per million** and **more non-Covid deaths per million than are associated with COVID-19**. An abundance of studies has shown that the mRNA vaccines are neither safe nor effective, but outright dangerous. Never in vaccine history have we seen 1011 case studies showing side effects of a vaccine…

Whistleblowers: … The question is how many deaths and side effects are we accepting as normal for vaccines and where do we draw the line to say more investigations need to be done before any further vaccines are distributed?

Conclusion: Never in Vaccine history have 57 leading scientists and policy experts released a report questioning the safety and efficacy of a vaccine. They not only questioned the safety of the current Covid-19 injections, but were calling for an immediate end to all vaccination. Many doctors and scientists around the world have voiced similar misgivings and warned of consequences due to long-term side effects. Yet there is no discussion or even mention of studies that do not follow the narrative on safety and efficacy of Covid-19 vaccination."

[724] **ADDED since 2/8/2022**

The Time of COVID

A Report by Phillip M. Altman, BPharm(Hons), MSc, PhD
Clinical Trial & Pharmaceutical Regulatory Affairs Consultant
August 9, 2022
https://amps.redunion.com.au/hubfs/Altman%20Report%20Version%209-8-22%20FINAL%20FINAL_%20(1).pdf

"**Foreword**: I am pleased and proud to endorse the attached letter and monograph, meticulously compiled by Dr Phillip Altman and his colleagues. They address some important aspects of COVID19 management and policy, especially in Australia, with a focus on the nature, deployment and effects of 'vaccines'. It is abundantly clear that there has been repression and suppression in scientific circles and the media of any views or suggestions that run counter to the government/mainstream narrative. However, many studies now indicate that the Covid19 vaccines, especially the mRNA vaccines, are less than 'safe and effective', and the ramifications are truly confronting. Armed with these facts, the scientific and medical communities can now begin proper discussions of potential solutions that improve the benefit/risk ratios for the public and do not harm careers and livelihoods of professionals seeking the best outcomes for their patients.

Wendy Hoy AO FAA FRACP
Professor of Medicine
Director, Centre for Chronic Disease
University of Queensland
Brisbane, Australia"

[725] ***Letter from Senator Ron Johnson to Lloyd J. Austin III, Secretary of the Department of Defense***
February 1, 2022
https://www.ronjohnson.senate.gov/services/files/FB6DDD42-4755-4FDC-BEE9-50E402911E02

"Dear Secretary Austin: On January 24, 2022, I held a roundtable featuring world renowned doctors and medical experts who shared their perspectives on COVID-19 vaccine efficacy and safety and the overall response to the pandemic. At that roundtable, I heard testimony from Thomas Renz, an attorney who is representing three Department of Defense (DoD) whistleblowers, who revealed disturbing information regarding dramatic increases in medical diagnoses among military personnel. The concern is that these increases may be related to the COVID-19 vaccines that our servicemen and women have been mandated to take.

Based on data from the Defense Medical Epidemiology Database (DMED), Renz reported that these whistleblowers found a **significant increase in registered diagnoses on DMED for miscarriages, cancer, and many other medical conditions in 2021 compared to a five-year average from 2016-2020**. For example, at the roundtable Renz stated that registered diagnoses for neurological issues increased 10 times from a five-year average of 82,000 to 863,000 in 2021. There were also increases in registered diagnoses in 2021 for the following medical conditions [*emphasis added*]:

- Hypertension – 2,181% increase
- Diseases of the nervous system – 1,048% increase
- Malignant neoplasms of esophagus – 894% increase
- Multiple sclerosis – 680% increase
- Malignant neoplasms of digestive organs – 624% increase
- Guillain-Barre syndrome – 551% increase
- Breast cancer – 487% increase
- Demyelinating – 487% increase
- Malignant neoplasms of thyroid and other endocrine glands – 474% increase
- Female infertility – 472% increase
- Pulmonary embolism – 468% increase
- Migraines – 452% increase
- Ovarian dysfunction – 437% increase
- Testicular cancer – 369% increase
- Tachycardia – 302% increase"

[726] ***New VAERS analysis reveals hundreds of serious adverse events that the CDC and FDA never told us about***
Steve Kirsch and Albert Benavides
November 9, 2021
https://stevekirsch.substack.com/p/new-vaers-analysis-reveals-hundreds
Team of Vaccine Safety Experts: https://stevekirsch.substack.com/p/my-team-of-vaccine-safety-experts

For excerpts, see [624]

[727] ***Comprehensive investigations revealed consistent pathophysiological alterations after vaccination with COVID-19 vaccines***
Cell Discovery – Nature (Tongji University, Shanghai)
Jiping Liu, Junbang Wang, *et al*.
October 26, 2021
https://www.nature.com/articles/s41421-021-00329-3

"**Abstract**: Large-scale COVID-19 vaccinations are currently underway in many countries in response to the COVID-19 pandemic. Here, we report, besides generation of neutralizing antibodies, consistent alterations in hemoglobin A1c, serum sodium and potassium levels, coagulation profiles, and renal functions in healthy volunteers after vaccination with an inactivated SARS-CoV-2 vaccine. Similar changes had also been reported in COVID-19 patients, suggesting that vaccination mimicked an infection. Single-cell mRNA sequencing (scRNA-seq) of peripheral blood mononuclear cells (PBMCs) before and 28 days after the first inoculation also revealed consistent alterations in gene expression of many different immune cell types. Reduction of CD8+ T cells and increase in classic monocyte contents were exemplary. Moreover, scRNA-seq revealed increased NF-κB signaling and reduced type I interferon responses, which were confirmed by biological assays and also had been reported to occur after SARS-CoV-2 infection with aggravating symptoms. Altogether, our study recommends additional caution when vaccinating people with pre-existing clinical conditions, including diabetes, electrolyte imbalances, renal dysfunction, and coagulation disorders…

Discussion: This is a comprehensive investigation of the pathophysiological changes, including detailed immunological alterations in people after COVID-19 vaccination. Results indicated that vaccination, in addition to stimulating the generation of neutralizing antibodies, also influenced various health indicators including those related to diabetes, renal dysfunction, cholesterol metabolism, coagulation problems, electrolyte imbalance, **in a way as if the volunteers experienced an infection**. scRNA-seq of PBMCs from volunteers before and after vaccination revealed **dramatic changes in immune cell gene expression** [*emphasis added*], not only echoing some of the clinical laboratory measures but also suggestive of increased NF-κB-related inflammatory responses, which turned out to be mainly taking place in classical monocytes. Vaccination also increased classical monocyte contents. Moreover, the gene set positively contributing to MVS scores, also known to be associated with severe symptom development, was highly expressed in monocytes. Type I interferon (IFN-α/β) responses, supposedly beneficial against COVID-19, were downregulated after vaccination. In addition, the negative MVS genes were highly expressed in lymphocytes (T, B, and NK cells), yet showed reduced expression after vaccination. Together, these data suggested that after vaccination, at least by day 28, other than generation of neutralizing antibodies, **people's immune systems, including those of lymphocytes and monocytes,** were perhaps in a

more vulnerable state [*emphasis added*]…

Our study postulates that it is imperative to consider the potential long-term impact of vaccination to certain medical conditions or to general human health."

[728] **Letter to the Editor: *Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination***
Journal of Infection (James Cook University, UK)
Rachael K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, and David R. Chadwick
April 22, 2021
https://www.journalofinfection.com/article/S0163-4453(21)00277-2/fulltext

"This study of healthcare workers demonstrated that prior COVID-19, but not Long-COVID, was associated with increased risk of AEs [*adverse events*] following BNT162b2/Pfizer vaccination, although there was no relationship with duration since COVID-19 illness. Women and younger individuals were also more likely to report AEs. Our study adds to other reports supporting the wider understanding of AEs following COVID-19 vaccination. Importantly, given hesitancy surrounding recently developed COVID-19 vaccines, our findings may help inform those with previous COVID-19 of increased susceptibility to certain AEs. Our study also adds weight to the question of whether a second dose of mRNA vaccine is necessary in those with previous COVID-19, assuming effective immunity is established after the first dose. This is relevant, given that Tre-Hardy's and other studies have reported **worse AEs following second doses** of vaccine."

[729] ***Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey***
Life journal (University of Manchester, UK)
Alexander G. Mathioudakis, Murad Ghrew, *et al*.
March 17, 2021
https://www.mdpi.com/2075-1729/11/3/249

"**Abstract**: An online survey was conducted to compare the safety, tolerability and reactogenicity of available COVID-19 vaccines in different recipient groups. This survey was launched in February 2021 and ran for 11 days. Recipients of a first COVID-19 vaccine dose ≥7 days prior to survey completion were eligible. The incidence and severity of vaccination side effects were assessed. The survey was completed by 2002 respondents of whom 26.6% had a prior COVID-19 infection. A prior COVID-19 infection was associated with an **increased risk of any side effect** (risk ratio 1.08, 95% confidence intervals (1.05–1.11)), fever (2.24 (1.86–2.70)), breathlessness (2.05 (1.28–3.29)), flu-like illness (1.78 (1.51–2.10)), fatigue (1.34 (1.20–1.49)) and local reactions (1.10 (1.06–1.15)). It was also associated with an **increased risk of severe side effects leading to hospital care** (1.56 (1.14–2.12)). While mRNA vaccines were associated with a higher incidence of any side effect (1.06 (1.01–1.11)) compared with viral vector-based vaccines, these were generally milder ($p < 0.001$), mostly local reactions. Importantly, mRNA vaccine recipients reported a considerably lower incidence of systemic reactions (RR < 0.6) including anaphylaxis, swelling, flu-like illness, breathlessness and fatigue and of side effects requiring hospital care (0.42 (0.31–0.58)). Our study confirms the findings of recent randomised controlled trials (RCTs) demonstrating that COVID-19 vaccines are generally safe with limited severe side effects. For the first time, our study links prior COVID-19 illness with an increased incidence of vaccination side effects and

demonstrates that mRNA vaccines cause milder, less frequent systemic side effects but more local reactions."

Personal Testimonials and Documentaries on Vaccine Injuries

[730] **C19 Vax Reactions**
https://www.c19vaxreactions.com/
Letter to CDC & FDA, May 24, 2021:
https://www.c19vaxreactions.com/uploads/1/3/7/7/137732232/letter_initials_2.pdf
Testimonials: https://www.c19vaxreactions.com/real-testimonials.html
Q&A video interviews: https://www.c19vaxreactions.com/qa.html

"Who we are:

- We are a large and ever growing group of Americans who were previously healthy and have been seriously injured by the COVID vaccines (Pfizer, Moderna, J&J as well as Astra Zeneca in the clinical trial stage in the United States).
- We are pro-vaccine, pro-science and were excited for the opportunity to be vaccinated and to do our part in helping to end the pandemic.
- We are completely independent of any other organization."

[731] **Interviews with Injured Healthcare Workers**
April 30, 2021: https://www.bitchute.com/video/X0fov5PnPMwO/
August 2, 2021: https://www.bitchute.com/video/8I4NlpjAsaL3/

[732] **ADDED since 2/8/2022**
COVID Vaccine Injury Stories
Compilation of video testimonials.
https://community.covidvaccineinjuries.com/covid-vaccine-injury-stories/

[733] **ADDED since 2/8/2022**
Circle of Mamas — Compilation of COVID Vaccine Reactions
November 26, 2021
https://circleofmamas.com/health-news/compilation-of-covid-vaccine-reactions/

"Thousands of first-hand testimonies and media reports from around the world. Yet these represent only a very small fraction of those who have experienced adverse reactions post-vaccination."

[734] **ADDED since 2/8/2022**
Real Not Rare
Compilation of video testimonials.
https://www.realnotrare.com/

"**Mission Statement**: Our government asked us to do our part to stop the virus. We thought we were doing the right thing. Now we are injured, many severely. We are hurting, in pain, and losing our jobs. We are demanding our government do the right thing by acknowledging our injuries, as well as establish compensation for the tens of thousands who have been injured or have died."

[735] **Other video testimonials of COVID-19 vaccine injury**
https://1000covidstories.com/
http://seethetruth.club/evidence-of-vaccine-victims-in-video/
https://www.canwetalkaboutit.org/
Israel: https://www.youtube.com/watch?v=S4BpEr8gztU

[736] **ADDED since 2/8/2022**
Documentary (82m): *Anecdotals*
December 2022
https://www.anecdotalsmovie.com/

"**Synopsis**: In March 2021, after receiving my Pfizer shot, I couldn't feel the left side of my face for a month. Eighteen months later, electric shocks and muscle weakness continue. Unable to receive the 2nd dose, I am amongst a group of partially-vaccinated people who have been outcast from many aspects of society with no empathy. We've been censored and told it's unethical to talk about our stories because we are just anecdotes.

This movie provides a glimpse into the lives of the Anecdotals–those of us whose lives have been changed drastically by taking the vaccine. It also reflects on the division and politics that prevents us from getting much needed care. Anecdotals is a personal journey that focuses on questions, not answers, and people, not politics."

[737] **ADDED since 2/8/2022**
Documentary (82m): *Safe and Effective – A Second Opinion*
October 2022
https://www.oraclefilms.com/safeandeffective

"*Safe and Effective: A Second Opinion* shines a light on Covid-19 vaccine injuries and bereavements, but also takes an encompassing look at the systemic failings that appear to have enabled them. We look at leading analysis of pharmaceutical trials, the role of the MHRA in regulating these products, the role of the SAGE behavioural scientists in influencing policy and the role of the media and Big Tech companies in supressing free and open debate on the subject."

[738] **ADDED since 2/8/2022**
Documentary (24m): *Silent No More*
Silent No More, New Zealand
https://rumble.com/v21ahhm-new-zealand-documentary-memorial-day-silent-no-more-nz.html

Description by Dr. Peter McCullough:
https://petermcculoughmd.substack.com/p/silent-no-more-nz

> "[*New Zealand*] has taken one of the most draconian approaches to mass vaccination. By threatening 'No Jab, No Job' Prime Minister Jacinda Ardern has managed to force >90% into COVID-19 vaccination.
>
> As a result, there are visible signs of vaccine injuries, disability, and death occurring as the effects of repeated injections set in. The film 'Silent No More' gives a horrifying real world depiction of the choreoathetosis or large oscillation involuntary movements."

[739] ***How concerned are you about adverse events related to the vaccines? Tell us what you think – your expectations and concerns.***
Medscape
https://www.medscape.com/sites/public/covid-19/vaccine-insights/how-concerned-are-you-about-vaccine-related-adverse-events
Note: Medscape post with more than 2,700 comments by medical professionals.

> "Commenting is limited to medical professionals."

Blood Clotting and other Circulatory-System Issues

Definitions:

"**thrombus**: a stationary blood clot along the wall of a blood vessel, frequently causing vascular obstruction."
https://medical-dictionary.thefreedictionary.com/thrombus

"**thrombosis**: formation, development, or presence of a thrombus; this can happen whenever the flow of blood in arteries or veins is impeded."
https://medical-dictionary.thefreedictionary.com/thrombosis

"**thrombocytopenia** is a blood disease characterized by an abnormally low number of platelets in the bloodstream."
https://medical-dictionary.thefreedictionary.com/thrombocytopenia

"**portal vein thrombosis (PVT)** is a vascular disease of the liver that occurs when a blood clot occurs in the hepatic portal vein, which can lead to increased pressure in the portal vein system and reduced blood supply to the liver."
https://encyclopedia.thefreedictionary.com/portal+vein+thrombosis

"**cerebral venous sinus thrombosis (CVST)** is the presence of a blood clot in the dural venous sinuses, which drain blood from the brain. Symptoms may include headache, abnormal vision, any of the symptoms of stroke such as weakness of the face and limbs on one side of the body, and seizures."
https://encyclopedia.thefreedictionary.com/cerebral+venous+sinus+thrombosis

"**hemagglutination** is a reaction that causes clumping of red blood cells in presence of some enveloped viruses, such as the influenza virus. A glycoprotein on the viral surface, namely hemagglutinin, interacts with red blood cells, leading to the clumping of red blood cells and the formation of a lattice."
https://www.news-medical.net/health/An-Overview-of-Hemagglutination.aspx

vaccine-induced immune thrombotic thrombocytopenia (VITT)
"Beginning in March 2021, otherwise healthy individuals developed complications starting 5 to 20 days following receipt of [*the Astrazeneca or Janssen COVID-19 vaccine*]… Key features were cerebral venous sinus thrombosis (CVST), splanchnic vein thrombosis, or other often severe thrombotic events in combination with thrombocytopenia."
https://www.sciencedirect.com/science/article/pii/S0037196322000075?via%3Dihub

Note: The citations below are presented in reverse, chronological order.

[740] **ADDED since 2/8/2022**
U.S. FDA, CDC see early signal of possible Pfizer bivalent COVID shot link to stroke
Reuters
Bhanvi Satija
January 14, 2023
https://www.reuters.com/business/healthcare-pharmaceuticals/us-says-pfizers-bivalent-covid-shot-may-be-linked-stroke-older-adults-2023-01-13/

> "The U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) said on Friday that a CDC vaccine database had uncovered a possible safety issue in which people 65 and older were more likely to have an ischemic stroke 21 days after receiving the Pfizer/BioNTech bivalent shot, compared with days 22-44."

[741] **ADDED since 2/8/2022**
SARS-CoV-2 Spike Protein Induces Hemagglutination: Implications for COVID-19 Morbidities and Therapeutics and for Vaccine Adverse Effects
Hôpitaux de Marseille
Celine Boschi, David E. Scheim, *et al*.
November 28, 2022
https://www.biorxiv.org/content/10.1101/2022.11.24.517882v1.full

> "**Abstract**: Experimental findings for SARS-CoV-2 related to the glycan biochemistry of coronaviruses indicate that attachments from spike protein to glycoconjugates on the surfaces of red blood cells (RBCs), other blood cells and endothelial cells are key to the infectivity and morbidity of COVID-19. To provide further insight into these glycan attachments and their potential clinical relevance, the classic hemagglutination (HA) assay was applied using spike protein from the Wuhan, Alpha, Delta and Omicron B.1.1.529 lineages of SARS-CoV-2 mixed with human RBCs… The results of these experiments were, first, that **spike protein** from these four lineages of SARS-CoV-2 **induced HA**... **IVM [*ivermectin*] blocked HA** when added to RBCs prior to spike protein and **reversed HA** when added afterwards. These results validate and extend prior findings on the role of glycan bindings of viral spike protein in COVID-19. They furthermore suggest therapeutic options using competitive glycan-binding agents such as IVM and may help elucidate rare serious adverse effects (AEs) associated with COVID-19 mRNA vaccines which use spike protein as the generated antigen…
>
> **Discussion**: … The HA-inducing activity of SARS-CoV-2 spike protein, which is especially potent for Omicron, raises questions as to potential risks for COVID-19 mRNA vaccines, which use spike protein as the generated antigen, even though serious adverse effects (AEs) linked to spike protein, such as myocarditis,64-66 are rare. Detectable levels of SARS-CoV-2 spike protein and S1 in serum or plasma have been found to persist as long as 50 days following such vaccinations. The possibility that spike protein migrating into the blood stream could in rare cases prompt such HA-associated AEs is suggested, for example, by a study of 1,006 subjects experiencing AEs after receiving a Pfizer/BioNTech or Moderna mRNA vaccination which **found a significant degree of RBC aggregation in the blood of 948 of those subjects**. These risks may be increased for younger age groups, with **301 adolescents of 13-18 years of age** who received two doses of the BNT162b2 mRNA COVID-19 vaccine in one study **having a 29.2% rate of cardiac AEs**, ranging from

tachycardia or palpitation to myopericarditis. The investigators considered chest pain, which occurred at a 4% incidence, 'an alarming side effect,' however myopericarditis cases were mostly mild and temporary."

[742] **ADDED since 2/8/2022**

#Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) — Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

Janssen Pharmaceutical Companies
Revised May 5, 2022
https://www.fda.gov/media/146304/download

"WARNING: THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME

See Full EUA Prescribing Information for complete warning.

The Janssen COVID-19 Vaccine can cause **thrombosis with thrombocytopenia syndrome (TTS)** which may be life-threatening.

TTS may involve thrombosis at unusual locations for a thrombus (i.e., cerebral vein, visceral artery or vein, extremity artery, central artery or vein) or in an extremity vein or pulmonary artery.

Among reported cases of TTS following administration of the Janssen COVID-19 Vaccine, symptoms began approximately one to two weeks after vaccination."

[743] **ADDED since 2/8/2022**

COVID-19 and the Unraveling of Experimental Medicine - Part II

The Gazette of Medical Science
K.E. Thorp, James A. Thorp, and Elise M. Thorp
March 10, 2022
https://www.thegms.co/publichealth/pubheal-rw-22022804.pdf

"By Spring 2021 reports began to trickle in describing a rash of clotting disorders, both arterial and venous, occurring days to weeks following vaccination. Such events also occur in COVID-19 infections. Arterial thromboses present as heart attack or stroke. In addition to the more common venous thromboses in the lower extremities, **vaccine-related clotting occurs in atypical locations like cerebral sinuses and intestinal veins**. (Figure 1) Venous thrombosis, in turn, leads to a higher incidence of pulmonary embolism. (Figure 2) Such events prompted the temporary withdrawal of the J & J vaccine in Europe and the US.

Laboratory data pointed toward an immune-mediated process. Thrombosis is associated with low blood platelet levels suggesting a consumptive process. Vaccine-induced thrombosis and thrombocytopenia (VITT) is strikingly similar to heparin-induced thrombocytopenia (HIT) in which administered heparin induces autoantibody formation against platelet factor-4 (PF4). The heparin-PF4-immune complex triggers release of pro-thrombotic substances by platelets that induce clot formation throughout the vascular tree. In the process platelets are consumed which, subsequently, increases the risk for bleeding.

Platelet-activating antibodies against PF4 are present in VITT. The same hypercoagulable conditions, with or without PF4 autoantibodies, are present in COVID-19 infections. Besides

triggering platelets to release pro-clotting factors, anti-PF4 antibodies induce neutrophils to release NETs which promote inflammation, immune-mediated thrombosis, and end-organ damage associated with both COVID-19 infection and HIT. And, not surprisingly, NET formation also occurs in VITT. The common thread that ties VITT and COVID-19-related thrombosis together is **endothelial inflammation**, **diastolic dysfunction** and **impaired energy generation**.

Given such evidence, we are again led to question the logic behind mRNA vaccines. Why would scientists continue to employ an agent that induces inflammation, immune dysfunction, and vascular thrombosis, the same pathophysiological effects as viral infection, while at the same time conferring only temporary protection that is qualitatively inferior to natural infection? One can only wonder."

[744] **ADDED since 2/8/2022**

Video (5m): Steve Kirsch interview with embalmer Cary Watkins

Cary Watkins, licensed embalmer
Steve Kirsch, Executive Director of the Vaccine Safety Research Foundation
February 14, 2022
https://rumble.com/vuycmg-embalmer-with-50-years-of-experience-verifies-hirschmans-story.html

Kirsch: "So you've actually seen these clots yourself that he [*Richard Hirschman*] has been talking to you about?" See [746].

Watkins: "Yes, sir, I have."

Kirsch: "Have you ever seen anything like that in your 50 years of embalming?"

Watkins: "Well, no sir, I don't believe so. I've seen clots but these are a little different and I've just not seen anything like that…"

[745] **ADDED since 2/8/2022**

Video (69m): Steve Kirsch interview with embalmer Anna Foster

Anna Foster, licensed embalmer with Foster Family Funeral Chapel & Cremation Services in Carrollton, Missouri
Steve Kirsch, Executive Director of the Vaccine Safety Research Foundation
February 12, 2022
https://rumble.com/vuqk1w-explosive-embalmer-reveals-93-of-cases-have-deadly-clots-caused-by-the-vax.html

From 1:30 to 5:00:

Kirsch: "You started seeing these weird clot formations that we talked about that other embalmers have seen, and you started seeing them eight months ago… You started seeing them in May or June of last year?"

Foster: "Yes, that's what I can pinpoint…. We have embalming reports that we fill out and I started noting on the reports, on each person, that I would begin to see these fibrous-looking clots, very large fibrous-looking clots, and I do have reports to verify the cases that I have seen them on."

Foster: "I've asked two of my very close friends that are embalmers… and they have both seen the same thing…"

Kirsch: "And you mentioned that in 28 of the last 30 cases that you've done, you've seen these strange clots?

Foster: "Yes. Yes."

Kirsch: "So 28 out of 30. So for our listeners, that's 93% of the last 30 people who died… had these clots. And you're aware of the vaccination status of most of these cases or all of these cases?

Foster: "Most of them, I am…"

Kirsch: "So have you ever seen these clots in someone who you know is not vaccinated?"

Foster: "No."

Kirsch: "And has the rate changed since you started seeing these back in the middle of last year?..."

Foster: "… Now it's more prominent. It's about every case that I get that is vaccinated."

[746] **ADDED since 2/8/2022**

Video (52m): Steve Kirsch interview with embalmer Richard Hirschman
Richard Hirschman, Funeral Director and licensed embalmer
Steve Kirsch, Executive Director of the Vaccine Safety Research Foundation
February 12, 2022
https://rumble.com/vuqk1w-explosive-embalmer-reveals-93-of-cases-have-deadly-clots-caused-by-the-vax.html
Alabama Active License Funeral Directors and Embalmers (2013):
https://www.fsb.alabama.gov/pdfs/2013/AlabamaActiveLicenseFuneralDirectorsandEmbalmers020113.pdf

Hirschman: "When COVID started back in early 2020, we did notice an increase in clotting during the COVID pandemic, but when January 2021 came around, it got really busy. We were running around like crazy, embalming lots of people, COVID and non-COVID, and then it was probably around May or June of last year, I started noticing I'm getting clots in the arteries, I'm getting long clots that are holding together and there's some strength to them, they're not typical clots that fall apart when you hold on to them with a forcep…"

Kirsch: "So you said you started getting busy around January 2021, that's the same time as when the vaccines rolled out. Did you get busier because there were more deaths that started happening relative to the deaths in 2020?"

Hirschman: "Um, yes. In January of 2020, I embalmed roughly about 38 people that month. But in January of 2021, I embalmed 101… And it was busy for everybody around here."

Hirschman: "… I have many different photographs because sometimes the clots are small. But again, there's many of them when they're small. There's just a difference in the way the blood looks when you're doing the embalming process… I've had the blood so think that it would literally stick to my gloves, which was really strange… I've never had that happen before… There was one that was literally almost the length of the person's leg."

Kirsch: "So you've never seen these types of clots in someone you knew to be unvaccinated? Is that correct?"

Hirschman: "That's correct..."

Kirsch: "Do you know of any embalmer who is not seeing this?"

Hirschman: "No."

Kirsch: "How many embalmers have you talked to?"

Hirschman: "… Probably about 15 embalmers."

Kirsch: "And 15 out of 15 are seeing what you're seeing?"

Hirschman: "Yes…"

Kirsch: "… This is happening on a massive scale to, you know you said, your current numbers were like…"

Hirschman: "About 60%."

Kirsch: "No, 65%, based on the numbers you gave me. 37 out of 57 in January… So 65% of the cases you saw in 2022."

[747] **ADDED since 2/8/2022**

Portal Vein Thrombosis Might Develop by COVID-19 Infection or Vaccination: A Systematic Review of Case-Report Studies

Frontiers in Medicine — Birjand University of Medical Sciences, Birjand, Iran
Setare Kheyrandish, Amirhossein Rastgar, Morteza Arab-Zozani, and Gholamreza Anani Sarab
December 14, 2021
https://www.frontiersin.org/articles/10.3389/fmed.2021.794599/full

"**Background and Objective**: Infection by the novel coronavirus disease 2019 (COVID-19) has been associated with different types of thrombotic complications same as portal vein thrombosis (PVT). However, by emerging vaccines of COVID, the thrombosis did not seem to be concerning anymore. Until new findings showed that, **the vaccine of COVID itself can cause PVT**.

Method: We performed an electronic search in PubMed, Scopus, and Web of Sciences to evaluate the possibility of occurring PVT due to infection and vaccination of COVID-19. The results were reported in a narrative method and categorized into tables.

Result: Overall, 40 cases of PVT from 34 studies were reviewed in this article. The prevalence of PVT following COVID-19 was more remarkable in males. However, it was more common in females after vaccinations of COVID-19 in the reviewed cases. Regardless of etiology, 20 of PVT cases reviewed in this article had at least one comorbidity. The most common clinical presentation was abdominal pain (AP). After anticoagulant therapies, most of the patients improved or discharged.

Conclusion: As long as the laboratory findings are not appropriate enough to predict PVT, the diagnosis of this complication with whatever underlying reason is challengeable, while rapid diagnosis and treatment of that are vital. Therefore, by providing available data in an

organized way, we aimed to prepare the information of infected patients for better and easier future diagnosis of PVT in new cases."

[748] **ADDED since 2/8/2022**
Video (7m): *Funeral Director Tells All*
John O'Looney, Funeral Director of Milton Keynes Family Services (UK)
December 6, 2021
https://odysee.com/@ARGONAUT:d/FuneralDirectorTellsAll:3
About John: https://www.mkffs.co.uk/about-us

"What we're seeing is … an unnaturally large number of deaths due to heart attack, stroke, aneurysm, and these are all as a direct result of thrombosis embolisms in the lungs, the legs, various places that are causing these deaths. These are well-documented by the local coroners. These are well-documented across the country. But nobody seems concerned about the alarming rise in them.

I used to see a blood clot very, very rarely, and now I've seen more this year than I have in the previous 14."

[749] **ADDED since 2/8/2022**
Insights in ChAdOx1 nCoV-19 vaccine-induced immune thrombotic thrombocytopenia
Blood — University Medicine Greifswald, Germany
Andreas Greinacher, Kathleen Selleng, et al.
December 2, 2021
https://ashpublications.org/blood/article/138/22/2256/477080/Insights-in-ChAdOx1-nCoV-19-vaccine-induced-immune

"**Abstract**: SARS-CoV-2 vaccine ChAdOx1 nCoV-19 (AstraZeneca) causes a thromboembolic complication termed vaccine-induced immune thrombotic thrombocytopenia (VITT). Using biophysical techniques, mouse models, and analysis of VITT patient samples, we identified determinants of this vaccine-induced adverse reaction. Super-resolution microscopy visualized vaccine components forming antigenic complexes with platelet factor 4 (PF4) on platelet surfaces to which anti-PF4 antibodies obtained from VITT patients bound. PF4/vaccine complex formation was charge-driven and increased by addition of DNA. Proteomics identified substantial amounts of virus production-derived T-REx HEK293 proteins in the ethylenediaminetetraacetic acid (EDTA)-containing vaccine. Injected vaccine increased vascular leakage in mice, leading to systemic dissemination of vaccine components known to stimulate immune responses. Together, PF4/vaccine complex formation and the vaccine-stimulated proinflammatory milieu trigger a pronounced B-cell response that results in the formation of high-avidity anti-PF4 antibodies in VITT patients. The resulting high-titer anti-PF4 antibodies potently activated platelets in the presence of PF4 or DNA and polyphosphate polyanions. Anti-PF4 VITT patient antibodies also stimulated neutrophils to release neutrophil extracellular traps (NETs) in a platelet PF4-dependent manner. Biomarkers of procoagulant NETs were elevated in VITT patient serum, and NETs were visualized in abundance by immunohistochemistry in cerebral vein thrombi obtained from VITT patients. Together, **vaccine-induced PF4/adenovirus aggregates** and **proinflammatory reactions** stimulate pathologic anti-PF4 antibody production that drives thrombosis in VITT. The data support a 2-step mechanism underlying VITT that resembles the pathogenesis of (autoimmune) heparin-induced thrombocytopenia."

[750] **ADDED since 2/8/2022**

COVID-19 Vaccine-Related Thrombosis: A Systematic Review and Exploratory Analysis

Frontiers in Immunology — University of Palermo, Italy
Clio Bilotta, Biulio Perrone, *et al*.
November 29, 2021
https://www.frontiersin.org/articles/10.3389/fimmu.2021.729251/full

"**Introduction**: The World Health Organization declared the coronavirus disease 2019 (COVID-19) pandemic on March 11, 2020. Two vaccine types were developed using two different technologies: viral vectors and mRNA. Thrombosis is one of the most severe and atypical adverse effects of vaccines. This study aimed to analyze published cases of thrombosis after COVID-19 vaccinations to identify patients' features, potential pathophysiological mechanisms, timing of appearance of the adverse events, and other critical issues…

Discussion: **Vaccine-induced thrombotic thrombocytopenia (VITT)** is an unknown nosological phenomenon secondary to inoculation with the COVID-19 vaccine. Several hypotheses have been formulated regarding its physiopathological mechanism. Recent studies have assumed a mechanism that is assimilable to heparin-induced thrombocytopenia, with protagonist antibodies against the PF4–polyanion complex. Viral DNA has a negative charge and can bind to PF4, causing VITT. New experimental studies have assumed that **thrombosis is related to a soluble adenoviral protein spike variant**, originating from splicing events, which cause important endothelial inflammatory events, and binding to endothelial cells expressing ACE2."

[751] **Research Letter: *Age- and Sex-Specific Incidence of Cerebral Venous Sinus Thrombosis Associated With Ad26.COV2.S COVID-19 Vaccination***

JAMA Internal Medicine (Mayo Clinic)
Aneel A. Ashrani, Daniel J. Crusan, *et al*.
November 1, 2021
https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2785610
What is cerebral venous sinus thrombosis? "Cerebral venous sinus thrombosis (CVST) occurs when a blood clot forms in the brain's venous sinuses. This prevents blood from draining out of the brain. As a result, blood cells may break and leak blood into the brain tissues, forming a hemorrhage." (Source Johns Hopkins)

"Recent reports suggest a possible association between Ad26.COV2.S (Johnson & Johnson/Janssen) COVID-19 vaccination and cerebral venous sinus thrombosis (CVST). Estimates of postvaccination CVST risk require accurate age- and sex-specific prepandemic CVST incidence rates; however, reported rates vary widely. We compared the age- and sex-specific CVST rates after Ad26.COV2.S vaccination with the prepandemic CVST rate in the population…

Results: … The overall [*prepandemic*] age- and sex-adjusted CVST incidence was **2.34** per 100 000 person-years (PY)…

The overall incidence rate of post–Ad26.COV2.S vaccination CVST was **8.65** per 100 000 PY (95% CI, 5.88-12.28 per 100 000 PY) at 15 days, **5.02** per 100 000 PY (95% CI, 3.52-6.95 per 100 000 PY) at 30 days…"

[752] **ADDED since 2/8/2022**

COVID-19 Vaccine-Associated Thrombosis With Thrombocytopenia Syndrome (TTS): A Systematic Review and Post Hoc Analysis

Clinical and Applied Thrombosis/Hemostasis (SAGE Journals)
Muhammad Usman Hafeez, Maha Ikram, *et al*.
October 26, 2021
https://journals.sagepub.com/doi/10.1177/10760296211048815

"**Background**: A new clinical syndrome has been recognized following the COVID-19 vaccine, termed **thrombosis with thrombocytopenia syndrome (TTS)**. The following systematic review focuses on extrapolating thrombotic risk factors, clinical manifestations, and outcomes of patients diagnosed with TTS following the COVID-19 vaccine…

Conclusion: Adenoviral COVID-19 vaccines have been shown to trigger TTS, however, reports of patients having received mRNA COVID-19 vaccines are also present. Healthcare providers are recommended to maintain a high degree of suspicion among individuals who have received the COVID-19 vaccine within the last 4 weeks."

[753] ***SARS-CoV-2 spike protein induces abnormal inflammatory blood clots neutralized by fibrin immunotherapy***

Gladstone Institute and the University of California San Francisco
Jae Kyu Ryu, Elif G. Sozmen, *et al*.
October 13, 2021
https://www.biorxiv.org/content/10.1101/2021.10.12.464152v1.full

"**Abstract**: Blood clots are a central feature of coronavirus disease-2019 (COVID-19) and can culminate in pulmonary embolism, stroke, and sudden death. However, it is not known how abnormal blood clots form in COVID-19 or why they occur even in asymptomatic and convalescent patients. Here we report that the Spike protein from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) binds to the blood coagulation factor fibrinogen and induces structurally abnormal blood clots with heightened proinflammatory activity. SARS-CoV-2 Spike virions enhanced fibrin-mediated microglia activation and induced fibrinogen-dependent lung pathology. COVID-19 patients had fibrin autoantibodies that persisted long after acute infection. Monoclonal antibody 5B8, targeting the cryptic inflammatory fibrin epitope, inhibited thromboinflammation. Our results reveal a procoagulant role for the SARS-CoV-2 Spike and propose fibrin-targeting interventions as a treatment for thromboinflammation in COVID-19.

One-Sentence Summary: SARS-CoV-2 spike induces structurally **abnormal blood clots** and **thromboinflammation** [*emphasis added*] neutralized by a fibrin-targeting antibody."

[754] ***Vaccine-induced immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis post COVID-19 vaccination; a systematic review***

Journal of Neurological Sciences
Maryam Sharifian-Dorche, Mohammad Bahmanyar, *et al*.
September 15, 2021
https://www.sciencedirect.com/science/article/pii/S0022510X21003014

"**Introduction**: … The common reported adverse effects of COVID-19 vaccination consist of the injection site's local reaction followed by several non-specific flu-like symptoms. However,

rare cases of vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST) after viral vector vaccines (ChAdOx1 nCoV-19 vaccine, Ad26.COV2 vaccine) have been reported. Herein we systemically reviewed the reported cases of CVST and VITT following the COVID-19 vaccination…

Results: Until May 19, we found 877 articles with the searched terms. We found 12 articles, which overall present clinical features of 36 patients with CVST and VITT after the ChAdOx1 nCoV-19 vaccine. Moreover, two articles were noted, which present 13 patients with CVST and VITT after Ad26.COV2 vaccine. The majority of the patients were females. Symptom onset occurred within one week after the first dose of vaccination (Range 4–19 days). Headache was the most common presenting symptom. Intracerebral hemorrhage (ICH) and/or Subarachnoid hemorrhage (SAH) were reported in 49% of the patients. The platelet count of the patients was between 5 and 127 cells×109/l, PF4 IgG Assay and d-Dimer were positive in the majority of the reported cases. Among 49 patients with CVST, **at least 19 patients died (39%)** due to complications of CVST and VITT [*emphasis added*]."

[755] ***CVST After COVID-19 Vaccine: New Data Confirm High Mortality Rate***
Medscape
Sue Hughes
September 30, 2021
https://www.medscape.com/viewarticle/959992

"A new series of cases of cerebral venous sinus thrombosis (CVST) linked to the adenoviral vector COVID-19 vaccines has been reported, confirming the severity of the reaction and the associated high mortality rate.

This new series comes from an international registry of consecutive patients who experienced CVST within 28 days of COVID-19 vaccination between March 29 and June 18, 2021, from 81 hospitals in 19 countries…

'This is a reliable description on the clinical condition of these patients with CVST associated with COVID-19 vaccination. It is striking that this [*is*] a **much worse condition than CVST not associated with COVID-19 vaccination**, with a much higher rate of intracerebral hemorrhage and coma and a much higher mortality rate [*emphasis added*],' senior author Jonathan M. Coutinho, MD, Amsterdam University Medical Centers… told Medscape Medical News.'

These data confirm the observations from an earlier UK cohort in which cases of cerebral venous thrombosis linked to COVID-19 vaccination occurred…

In the cohort of 116 patients with CVST after COVID-19 vaccination, 78 (67.2%) had thrombosis with TTS [*thrombocytopenia syndrome*] and were thus classified as having had a vaccine-related adverse event. These patients were frequently comatose at presentation (24%) and often had intracerebral hemorrhage (68%) and concomitant thromboembolism (36%); 47% died during hospitalization...

Mortality rates were much higher among the patients deemed to have had a vaccine-related CVST. The in-hospital mortality rate was 47%, compared with 5% among the patients in the same cohort who did not have TTS and 3.9% among the prepandemic control group."

[756] ***Characteristics and Outcomes of Patients With Cerebral Venous Sinus Thrombosis in SARS-CoV-2 Vaccine–Induced Immune Thrombotic Thrombocytopenia***
JAMA Neurology
Mayte Sanchez van Kammen, Diana Aguiar de Sousa, *et al*.
September 28, 2021
https://jamanetwork.com/journals/jamaneurology/fullarticle/2784622

"**Conclusions and Relevance**: In this cohort study of patients with CVST, a distinct clinical profile and high mortality rate was observed in patients meeting criteria for TTS after SARS-CoV-2 vaccination."

[757] ***The Dangers of Covid-19 Booster Shots and Vaccines: Boosting Blood Clots and Leaky Vessels***
Doctors for COVID Ethics
September 17, 2021
https://doctors4covidethics.org/wp-content/uploads/2021/09/Vaccine-immune-interactions-and-booster-shots_Sep-2021.pdf
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

See 0

[758] ***COVID-19 vaccine: Strong association with cardiovascular death, especially hemorrhagic stroke and venous thrombosis***
Non-Profit Organization Japan Institute of Pharmacovigilance (NOPJIP)
Med Check Editorial Team
August 2021
https://www.npojip.org/english/MedCheck/Med%20Check%20Tip-20-2021-08&12.pdf

"**Abstract**:

- We analysed 196 death cases reported after inoculation of Pfizer-BioNTech COVID-19 vaccine (COMIRNATY) by June 9 in Japan…
- Of 31 deaths among vaccinated medical workers (both sexes), 26 (84%) died from cardiovascular diseases, such as stroke, myocardial infarction, venous thrombosis and pulmonary embolism (VT/PE) and heart failure, while 22% died in the general population. MOR [*mortality odds ratio*] is 19.4 ($p<0.0001$). MOR of hemorrhagic stroke (40.7) and VT/PE (114.0) were extremely high [*emphasis added*].
- Of the reported vaccinated elderly death cases, 69% died from cardiovascular causes, while 26% died in the general population. MOR is 5.9 ($p<0.0001$). MOR of hemorrhagic stroke (12.8) and VT/PE (24.9) were also very high.
- These suggest that COVID-19 vaccination is closely associated with the risk of death from cardiovascular causes, especially hemorrhagic stroke and VT/PE."

[759] **ADDED since 2/8/2022**

Comparison of adverse drug reactions among four COVID-19 vaccines in Europe using the EudraVigilance database: Thrombosis at unusual sites

Journal of Thrombosis and Hoemostasis — Bianchi Bonomi Hemophilia and Thrombosis Center, Italy

Maria Abbattista, Ida Martinelli, and Flora Peyvandi

August 9, 2021

https://www.jthjournal.org/article/S1538-7836(22)02170-5/fulltext

"**Background**: Real-world experience with adenoviral vector vaccines against COVID-19 raised some safety concerns. Cases of cerebral vein thrombosis (CVT) associated with thrombocytopenia have been observed after the first dose of the adenoviral vector vaccines CHADOX1 NCOV-19 and AD26.COV2.S.

Objectives: To assess the reporting rate of CVT as adverse drug reaction (ADR) for the COVID-19 vaccines authorized in Europe.

Patients and Methods: This observational study assessed the CVT reporting rate attributed to four COVID-19 vaccines authorized in Europe, namely Tozinameran (Pfizer-Biontech), CX-024414 (Moderna), CHADOX1 NCOV-19 (AstraZeneca), and AD26.COV2.S (Janssen). Data on thrombotic ADRs reported on EudraVigilance database between January 1, 2021 and July 30, 2021, were collected. ADRs referring to CVT were identified…

Results: The reporting rate of CVT per 1 million person vaccinated-days was 1.92 (95% confidence interval [CI], 1.71–2.12) for Tozinameran, 5.63 (95% CI, 4.74–6.64) for CX-024414, 21.60 (95% CI, 20.16–23.11) for CHADOX1 NCOV-19, and 11.48 (95% CI, 9.57–13.67) for AD26.COV2.S. CVT occurred alongside thrombocytopenia for the four vaccines. The OE [*observed-to-expected*] ratio was **greater than one for all four vaccines**, both with the lowest and the highest CVT background incidence.

Conclusions: This report on EudraVigilance data strengthens anecdotal findings on CVT following COVID-19 vaccinations. Although the European Medicines Agency released an alert only for CHADOX1 NCOV-19 and AD26.COV2.S, Tozinameran and CX-024414 also are complicated by CVT, albeit to lesser extent."

[760] ***Cerebral venous thrombosis after vaccination against COVID-19 in the UK: a multicentre cohort study***

The Lancet (NHS Foundation Trust)

Richard J. Perry, Arina Tamborska, *et al*.

August 6, 2021

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01608-1/fulltext

"**Background**: A new syndrome of vaccine-induced immune thrombotic thrombocytopenia (VITT) has emerged as a rare side-effect of vaccination against COVID-19. Cerebral venous thrombosis is the most common manifestation of this syndrome but, to our knowledge, has not previously been described in detail. We aimed to document the features of post-vaccination cerebral venous thrombosis with and without VITT and to assess whether VITT is associated with poorer outcomes…

Methods: For this multicentre cohort study, clinicians were asked to submit all cases in which COVID-19 vaccination preceded the onset of cerebral venous thrombosis, regardless of the type of vaccine, interval between vaccine and onset of cerebral venous thrombosis symptoms, or blood test results...

Added value of this study: To our knowledge, our report describes the largest study of cerebral venous thrombosis after vaccination against COVID-19. We can make the first direct comparison between 70 patients with VITT-associated cerebral venous thrombosis and 25 patients who developed cerebral venous thrombosis after vaccination but did not have VITT, in addition to secondary comparisons with a large historical cohort with cerebral venous thrombosis. Our results show, for the first time to our knowledge, that when they are compared with those without VITT, **patients with VITT-associated cerebral venous thrombosis were younger, had fewer venous thrombosis risk factors,** and **were more likely to have been given the ChAdOx1 vaccine**. They developed more extensive cerebral venous thrombosis with more veins or sinuses thrombosed, and multiple intracerebral haemorrhage was more common. They were more likely to have concurrent extracranial venous or arterial thromboses. Their outcomes at the end of hospital admission were worse, with **higher rates of death and disability** [*emphasis added*].

Implications of all the available evidence: VITT is specifically **associated with adenovirus vector vaccines against COVID-19** and urgent work is needed to elucidate the trigger for this reaction, in the hope that future vaccines can be designed to avoid this. Clinicians need to be aware of the clinical, laboratory, and radiological markers of this condition, as without prompt treatment the outcome is very poor [*emphasis added*]."

[761] ***Cerebral venous thrombosis after vaccination against COVID-19 in the UK: a multicentre cohort study***
The Lancet
Richard J. Parry, Arina Tamborska, *et al*.
August 6, 2021
https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2901608-1

"**Background**: A new syndrome of vaccine-induced immune thrombotic thrombocytopenia (VITT) has emerged as a rare side-effect of vaccination against COVID-19. Cerebral venous thrombosis is the most common manifestation of this syndrome but, to our knowledge, has not previously been described in detail. We aimed to document the features of post-vaccination cerebral venous thrombosis with and without VITT and to assess whether VITT is associated with poorer outcomes…

Interpretation: Cerebral venous thrombosis is more severe in the context of VITT…

Results: … **The primary outcome of death or dependency** [hospital staff needed] **occurred more frequently in patients with VITT-associated cerebral venous thrombosis** (33 [47 percent] of 70 patients) compared with the non-VITT control group (four [16 percent] of 25 patients; p=0·0061) [*emphasis added*]. More patients died during admission in the VITT-associated cerebral venous thrombosis group (20 [29 percent] of 70 patients) than in the non-VITT group (one [4 percent] of 25 patients; p=0·011)…

Discussion: [P]atients with VITT-associated cerebral venous thrombosis were younger than those without VITT. Other key findings were that, compared with non-VITT patients, those with

VITT-associated cerebral venous thrombosis had more extensive venous thrombosis and higher rates of multiple infarcts, multiple intra cerebral haemorrhages, and extracranial thrombosis. VITT was associated with significantly more death or dependency at the end of hospital admission."

[762] **Video (8m): Interview with Dr. Charles Hoffe**
July 7, 2021
https://www.bitchute.com/video/A6GbcUl6blpJ/

"The clots I'm talking about are microscopic at the capillary level, and they're scattered throughout your capillary network. So they're not going to show on any scan. They're just too small and too scattered. So the only way to find out if this particular mechanism of clotting was actually happening was to do this blood test called the D-dimer (which only shows new blood clots, not old blood clots)… So I have now been (testing patients) who have had their covid shots … between the previous four and seven days and doing (the D-dimer test)… On the ones I have so far, 62% of them have evidence of clotting, which means these blood clots are not rare… The most alarming part of this is that there are some parts of the body like the brain, spinal cord, heart and lungs which cannot re-generate. When those tissues are damaged by blocked vessels they are permanently damaged… These shots are causing huge damage and the worst is yet to come."

[763] ***Antibody epitopes in vaccine-induced immune thrombotic thrombocytopaenia***
Nature magazine
Angela Huynh, John G. Kelton, Donald M. Arnold, Mercy Daka, and Ishac Nazy
July 7, 2021
https://www.nature.com/articles/s41586-021-03744-4

"**Abstract**: … Our data indicate that VITT [*vaccine-induced immune thrombotic thrombocytopaenia*] antibodies can mimic the effect of heparin by binding to a similar site on PF4; this allows PF4 tetramers to cluster and form immune complexes, which in turn causes Fcγ receptor IIa (FcγRIIa; also known as CD32a)-dependent platelet activation. These results provide an explanation for VITT-antibody-induced platelet activation that could contribute to thrombosis."

[764] **ADDED since 2/8/2022**
Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination
New England Journal of Medicine — Medical University of Vienna
Andreas Greinacher , Thomas Thiel, *et al*.
June 3, 2021
https://www.nejm.org/doi/10.1056/NEJMoa2104840

"**Background**: Several cases of unusual thrombotic events and thrombocytopenia have developed after vaccination with the recombinant adenoviral vector encoding the spike protein antigen of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (ChAdOx1 nCov-19, AstraZeneca). More data were needed on the pathogenesis of this unusual clotting disorder.

Methods: We assessed the clinical and laboratory features of 11 patients in Germany and Austria in whom thrombosis or thrombocytopenia had developed after vaccination with ChAdOx1 nCov-19…

Results: Of the 11 original patients, 9 were women, with a median age of 36 years (range, 22 to 49). Beginning 5 to 16 days after vaccination, the patients presented with one or more thrombotic events, with the exception of 1 patient, who presented with fatal intracranial hemorrhage. Of the patients with one or more thrombotic events, 9 had cerebral venous thrombosis, 3 had splanchnic-vein thrombosis, 3 had pulmonary embolism, and 4 had other thromboses; of these patients, 6 died. Five patients had disseminated intravascular coagulation."

[765] **ADDED since 2/8/2022**

US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021

JAMA — Centers for Disease Control and Prevention COVID-19 Response Team
Isaac See, John R. Su, *et al*.
April 30, 2021
https://jamanetwork.com/journals/jama/fullarticle/2779731

"**Question**: What were the clinical characteristics of the first US patients reported to have cerebral venous sinus thrombosis (CVST) with thrombocytopenia following receipt of the Ad26.COV2.S (Janssen/Johnson & Johnson) COVID-19 vaccine?

Findings: In this case series of 12 patients, all were women, younger than 60 years, and had symptom onset ranging from 6 to 15 days after vaccination requiring hospitalization. Of 11 patients with heparin-platelet factor 4 enzyme-linked immunosorbent assay (ELISA) heparin-induced thrombocytopenia (HIT) antibody test results, all were positive. At last follow-up, outcomes were death (n = 3), intensive care unit (ICU) care (n = 3), non-ICU hospitalization (n = 2), and discharge to home (n = 4)."

[766] ***COVID-19 vaccine-induced immune thrombotic thrombocytopenia: An emerging cause of splanchnic vein thrombosis***

Annals of Hepatology
Mateo Porres-Aguilar, Alejandro Lazo-Langner, Arturo Pandura, and Misael Uribe
April 30, 2021
https://www.sciencedirect.com/science/article/pii/S1665268121000557

"[T]wards end of February 2021, a significant number of venous thromboses (VTE) in unusual sites (cerebral venous-sinus thrombosis [CVST], and splanchnic vein thrombosis [SVT]) in combination with thrombocytopenia were observed in individuals that received the Aztra Zeneca coronavirus disease 2019 (COVID-19) vaccine…

Investigators found that these thrombotic thrombocytopenic syndromes shared striking similarities with severe heparin-induced thrombocytopenia (HIT), a well-known hypercoagulable disorder caused by platelet-activating antibodies that recognize multimolecular complexes like those formed by PF-4 and anionic heparin, triggering prothrombotic events, with the exception that the above-described patients never were exposed to heparin, a variant known as autoimmune HIT...

Finally, authors proposed to name this new entity **Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)** [*emphasis added*]…

Several international societies, including the International Society for Thrombosis and Haemostasis (ISTH) have recently published their guidance for the diagnosis and management of VITT, which currently represents a 'rare entity/phenomenon', but can affect patients of all ages and both sexes.

We recommend that clinicians be familiarized and be extremely alert and raise awareness among other colleagues regarding the clinical and laboratory features that may trigger a clinical concern for VITT, having an exceptionally low threshold for further investigations in these patients since they could present with non-specific signs and symptoms of VTE in unusual sites like CVST or SVT."

[767] **Open Letter: *Doctors and Scientists Write to the European Medicines Agency, Warning of COVID-19 Vaccine Dangers for a Third Time***
Doctors for COVID Ethics
April 24, 2021
https://doctors4covidethics.org/doctors-and-scientists-write-to-the-european-medicines-agency-warning-of-covid-19-vaccine-dangers-for-a-third-time/
Signatories: https://doctors4covidethics.org/doctors-for-covid-ethics-signatories/

"Our most serious concern re ALL the gene-based vaccines is that you convey the impression that cerebral venous sinus thrombosis (CVST) *[ed. blood-clot formation in the brain's venous sinuses]* is a very rare adverse event. In fact **the opposite is probably true**. The cardinal symptoms of CVST dominate the list of adverse reactions: piercing headache, nausea and vomiting, impaired consciousness, impaired speech, impaired vision, impaired hearing, paralysis of varying degrees in various locations, and loss of motor control (including such severe loss that victims mimic the symptoms of Huntington's Chorea). It is imperative that proper medical attention is given to every individual who presents with any of the above symptoms. It is the indirigible duty of the European Medicines Agency to disseminate the above information to medical doctors and responsible authorities…

A further serious concern is that peripheral 'clot' formation is not alluded to by you at all. It is evident that 'clot' formation in the deep veins of the legs and arms can lead to life-threatening pulmonary embolism. Further, thrombus formation in the small vessels of the lungs can lead to a clinical picture resembling atypical pneumonia. In addition, it is vitally important to understand that any one of 1a. 1b. 1c. or any combination of these can lead via consumption of coagulation factors to the clinical picture of disseminated intravascular coagulation (DIC) which is actually characterised by massive bleeding events into the skin and into other organs of the body. It is imperative that all the above diagnoses are actively searched for and that all cases displaying symptoms consistent with any of these diagnoses are recorded properly as adverse vaccine-related events."

[768] ***Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination***
New England Journal of Medicine
Nina Schultz, Ingvild H. Servoll, *et al*.
April 9, 2021
https://www.nejm.org/doi/full/10.1056/NEJMoa2104882

"**Discussion**: … Although rare, VITT [*vaccine-induced immune thrombotic thrombocytopenia*] is a new phenomenon with devastating effects for otherwise healthy young adults and requires a thorough risk–benefit analysis. The findings of our study indicate that VITT may be more frequent than has been found in previous studies in which the safety of the ChAdOx1 nCoV-19 vaccine has been investigated."

[769] **ADDED since 2/8/2022**
Thrombocytopenia and Intracranial Venous Sinus Thrombosis after "COVID-19 Vaccine AstraZeneca" Exposure
Journal of Clinical Medicine — University of Heidelberg, Germany
Marc E. Wolf, Beate Luz, *et al*.
April 9, 2021
https://www.mdpi.com/2077-0383/10/8/1599

"**Objective**: To describe the clinical manifestations and the concerning management of patients with cranial venous sinus thrombosis following first exposure to the 'COVID-19 vaccine AstraZeneca'.

Methods: Patient files, laboratory findings, and diagnostic imaging results, and endovascular interventions of three concerning patients were evaluated in retrospect.

Results: Three women with intracranial venous sinus thrombosis after their first vaccination with 'COVID-19 vaccine AstraZeneca' were encountered. Patient #1 was 22 years old and developed headaches four days after the vaccination. On day 7, she experienced a generalized epileptic seizure. Patient #2 was 46 years old. She presented with severe headaches, hemianopia to the right, and mild aphasia 13 days after the vaccination. MRI showed a left occipital intracerebral hemorrhage. Patient #3 was 36 years old and presented 17 days after the vaccination with acute somnolence and right-hand hemiparesis. The three patients were diagnosed with extensive venous sinus thrombosis. They were managed by heparinization and endovascular recanalization of their venous sinuses. They shared similar findings: elevated levels of D-dimers, platelet factor 4 antiplatelet antibodies, corona spike protein antibodies, combined with thrombocytopenia. Under treatment with low-molecular-weight heparin, platelet counts normalized within several days.

Conclusion: Early observations insinuate that the exposure to the 'COVID-19 vaccine AstraZeneca' might trigger the expression of antiplatelet antibodies, resulting in a condition with thrombocytopenia and venous thrombotic events (e.g., intracranial venous sinus thrombosis). These patients' treatment should address the thrombo-embolic manifestations, the coagulation disorder, and the underlying immunological phenomena."

[770] ***Stage III Hypertension in Patients After mRNA-Based SARS-CoV-2 Vaccination***
Hypertension (American Heart Association)
Sylvain Meylan, Francoise Livio, *et al*.
March 25, 2021
https://www.ahajournals.org/doi/10.1161/HYPERTENSIONAHA.121.17316

> "We report a case series of 9 patients [*in Lausanne, Switzerland*] with stage III hypertension documented within minutes of vaccination during the first 30 days, of which 8 were symptomatic…
>
> Our case series suggests that a fraction of hypertensive patients may react with symptomatically significant increases in both systolic and diastolic blood pressure. A stress response is likely in view of the public debate, in addition to pain response and white coat effect—the latter being associated with age and female sex.2 However, the relatively low heart rate (median, 73 bpm) may soften this hypothesis…
>
> The mRNA vaccines have received intense scrutiny for immediate hypersensitivity reactions in the wake of an initial report signaling 21 cases of anaphylaxis.3 Hypertension, on the contrary, has not been mentioned explicitly as an adverse event in both safety/immunogenicity trials. However, both phase I/II and III clinical trials for the mRNA vaccines included predominantly younger populations with a mean and median age of 31 and 52 years for the BNT162b2 vaccine4 and 31 and 51 for the mRNA-1273 vaccine.5 Although more data are needed to understand the extent and the mechanism of hypertension after mRNA-based vaccination, our data indicate that in elderly patients with a history of hypertension or significant prior cardiovascular comorbidities, prevaccination control of blood pressure and post-vaccination monitoring, including symptom screening, may be warranted."

[771] ***Letter to EMA by Professsor Sucharit Bhakdi and colleagues***
Sucharit Bhakdi, Marco Chiesa, Stephen Frost, Margareta Griesz-Brisson, Martin Haditsch, Stefan Hockertz, Lissa Johnson, Ulrike Kämmerer, Michael Palmer, Karina Reiss, Andreas Sönnichsen, and Michael Yeadon
February 28, 2021
https://viruswaarheid.nl/belangrijk/letter-to-ema-28-february-2021/

See [392]

Heart Disorders

Definitions:

"**myocarditis**: an inflammatory disease of the heart muscle (myocardium) that can result from a variety of causes. While most cases are produced by a viral infection, an inflammation of the heart muscle may also be instigated by toxins, drugs, and hypersensitive immune reactions. Myocarditis is a rare but serious condition that affects both males and females of any age."
https://medical-dictionary.thefreedictionary.com/myocarditis

"**pericarditis**: an inflammation of the two layers of the thin, sac-like membrane that surrounds the heart. This membrane is called the pericardium, so the term pericarditis means inflammation of the pericardium."
https://medical-dictionary.thefreedictionary.com/Pericarditis

"**myopericarditis**: inflammation of both the myocardium and pericardium."
https://medical-dictionary.thefreedictionary.com/myopericarditis

"**cardiac arrhythmia**: any abnormality in the rate, regularity, or sequence of cardiac activation."
https://medical-dictionary.thefreedictionary.com/Cardiac+arrhythmia

"**tachycardia**: abnormally rapid heart rate, usually taken to be over 100 beats per minute."
https://medical-dictionary.thefreedictionary.com/tachycardia

[772] ***Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty (COVID-19 Vaccine, mRNA) and Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19***)
Food and Drug Administration (FDA)
Revised September 22, 2021
https://www.fda.gov/media/144414/download

"Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:
• severe allergic reactions
• non-severe allergic reactions such as rash, itching, hives, or swelling of the face
• myocarditis (inflammation of the heart muscle)
• pericarditis (inflammation of the lining outside the heart)
• injection site pain
• tiredness
• headache
• muscle pain
• chills
• joint pain
• fever
• injection site swelling
• injection site redness
• nausea
• feeling unwell
• swollen lymph nodes (lymphadenopathy)
• diarrhea

• vomiting
• arm pain
• fainting in association with injection of the vaccine
These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials."

[773] **ADDED since 2/8/2022**
Clinical Considerations: Myocarditis and Pericarditis after Receipt of COVID-19 Vaccines Among Adolescents and Young Adults
Centers for Disease Control and Prevention
Updated March 23, 2023
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

"Cases of myocarditis and pericarditis have occurred most frequently in adolescent and young adult males within 7 days after receiving the second dose of an mRNA COVID-19 vaccine; however, cases have also been observed after dose 1 and booster doses.

Data from the clinical trials of the Novavax COVID-19 Vaccine and global vaccine safety monitoring systems suggest an increased risk of myocarditis and pericarditis following Novavax vaccination. Data from post-authorization monitoring of Janssen COVID-19 Vaccine (Johnson & Johnson) suggest a possible increased risk of myocarditis and pericarditis following Janssen vaccination."

[774] **ADDED since 2/8/2022**
Video (1m): Interview with Dr. Aseem Molhotra
Epoch Times
March 19, 2023
https://twitter.com/vigilantfox/status/1637441779807973376

Molhotra: "I think all cardiovascular conditions have got worse because of the vaccines. Anything and everything that can go wrong with the heart has gone wrong with the heart as a result of these mRNA vaccines. There's no doubt about it."

[775] **ADDED since 2/8/2022**
Viral Myocarditis
StatPearls — University of California Riverside
Michael Kang, Venu Chippa, and Jason An
Last Update: September 6, 2022
https://www.ncbi.nlm.nih.gov/books/NBK459259/

"Myocarditis is an inflammatory process of the myocardium. It can present in the acute, subacute, or chronic phase with either focal or diffuse involvement of the myocardium. In the United States and other developed countries, viral infections are most frequently the cause of myocarditis…

In symptomatic patients, the presentation can be highly variable from generalized fatigue, malaise, chest pain, congestive heart failure (CHF), cardiogenic shock, arrhythmias, and even cardiac arrest…

All patients diagnosed or suspected to have acute myocarditis should be admitted to the hospital and be monitored for hemodynamic instability. Immediate complications of myocarditis include ventricular dysrhythmias, left ventricular aneurysm, CHF, and dilated cardiomyopathy. The **mortality rate** is up to 20% at 1 year and 50% at 5 years. Despite optimal medical management, overall mortality has not changed in the last 30 years."

[776] ***Myocarditis***
Society of Cardiovascular Angiography and Interventions (SCAI)
January 11, 2015
http://www.secondscount.org/pediatric-center/pediatric-detail?cid=d0c36202-3ca1-4ea3-9d39-1525b56a0a58#.YYmMai-B1aF

"If myocarditis is caused by a virus, it may improve on its own. Medications may help the heart undergo this healing process. If the myocarditis improves, the child can lead a normal life thereafter. It is believed that about one-third of patients with myocarditis get better, one-third stay the same with reduced heart function, and **the condition severely deteriorates in about one-third of patients** [*emphasis added*]."

[777] ***Myocarditis - Early Biopsy Allows for Tailored Regenerative Treatment***
Deutsches Ärzteblatt International
U. Kuhl and H. Schultheiss
May 18, 2012
https://www.aerzteblatt.de/int/archive/article/125908

"**Prognosis**: … Acute myocarditis mostly does not sufficiently respond to symptomatic medication for heart failure, and mortality is high in spite of treatment. The long-term disease course depends on the pathogen, the extent and type of inflammation, and the initial injury to the myocardium. Focal borderline myocarditis often undergoes spontaneous clinical healing if no serious heart failure developed initially. The early mortality of fulminant lymphocytic myocarditis requiring intensive care is in excess of 40% in the first 4 weeks. Untreated giant cell and eosinophilic myocarditis also have an extremely poor prognosis, with 4 year survival rates of less than 20%. Granulomatous necrotizing myocarditis is lethal if overlooked and untreated. Non-fulminant active myocarditis has a **mortality rate of 25% to 56% within 3 to 10 years**, owing to progressive heart failure and sudden cardiac death [*emphasis added*], especially if symptomatic heart failure manifests early on. In addition to impaired left ventricular (LV) and right ventricular (RV) function, virus persistence, chronic inflammation, and cardiodepressive autoantibodies are independent predictors of a poor prognosis."

Note: The citations below are presented in reverse, chronological order.

[778] **ADDED since 2/8/2022**
Clinical outcomes of myocarditis after SARS-CoV-2 mRNA vaccination in four Nordic countries: population based cohort study
BMJ Medicine
Anders Husby, Hanne Levdal Gulseth, *et al*.
February 1, 2023
https://bmjmedicine.bmj.com/content/2/1/e000373

"**Objective**: To investigate the clinical outcomes of myocarditis associated with mRNA vaccines against the SARS-CoV-2 virus compared with other types of myocarditis.

Design: Population based cohort study.

Setting: Nationwide register data from four Nordic countries (Denmark, Finland, Norway, and Sweden), from 1 January 2018 to the latest date of follow-up in 2022…

Results: In 2018-22, 7292 patients were admitted to hospital with new onset myocarditis, with **530 (7.3%)** categorised as having myocarditis associated with SARS-CoV-2 mRNA vaccination, **109 (1.5%)** with myocarditis associated with covid-19 disease, and 6653 (91.2%) with conventional myocarditis."

[779] **ADDED since 2/8/2022**
Changes of ECG parameters after BNT162b2 vaccine in the senior high school students
European Journal of Pediatrics — National Taiwan University
Shuenn-Nan Chiu, Yih-Sharng Chen, *et al*.
January 5, 2023
https://link.springer.com/article/10.1007/s00431-022-04786-0

"**Abstract**: The purpose of this study is to determine the ECG [*electrocardiogram*] parameter change and the efficacy of ECG screening for cardiac adverse effect after the second dose of BNT162b2 vaccine in young population. In December 2021, in cooperation with the school vaccination system of Taipei City government, we performed a ECG screening study during the second dose of BNT162b2 vaccines. Serial comparisons of ECGs and questionnaire survey were performed before and after vaccine in four male-predominant senior high schools. Among 7934 eligible students, 4928 (62.1%) were included in the study. The male/female ratio was 4576/352. In total, 763 students (**17.1%**) had at least one cardiac symptom after the second vaccine dose, mostly chest pain and palpitations."

[780] **ADDED since 2/8/2022**

Circulating Spike Protein Detected in Post–COVID-19 mRNA Vaccine Myocarditis

Circulation — Massachusetts General Hospital and Harvard Medical School

Lael M. Yonker, Zoe Swank, *et al*.

January 4, 2023

https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.122.061025

"**Background**: Cases of adolescents and young adults developing myocarditis after vaccination with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)–targeted mRNA vaccines have been reported globally, but the underlying immunoprofiles of these individuals have not been described in detail…

Results: … A notable finding was that markedly **elevated levels of full-length spike protein** (33.9±22.4 pg/mL), unbound by antibodies, **were detected in the plasma of individuals with postvaccine myocarditis**, whereas no free spike was detected in asymptomatic vaccinated control subjects (unpaired t test; P<0.0001).

Conclusions: Immunoprofiling of vaccinated adolescents and young adults revealed that the mRNA vaccine–induced immune responses did not differ between individuals who developed myocarditis and individuals who did not. However, free spike antigen was detected in the blood of adolescents and young adults who developed post-mRNA vaccine myocarditis, advancing insight into its potential underlying cause."

[781] **ADDED since 2/8/2022**

SARS-CoV-2 vaccine and increased myocarditis mortality risk: A population based comparative study in Japan

Japan Institute of Pharmocovigilance

Sintaroo Watanabe and Rokuro Hama

December 22, 2022

https://www.medrxiv.org/content/10.1101/2022.10.13.22281036v2.full-text

"**Conclusion: SARS-CoV-2 vaccination was associated with higher risk of myocarditis death**, not only in young adults but also in all age groups including the elderly. Considering healthy vaccinee effect, the risk may be **4 times or higher** than the apparent risk of myocarditis death. Underreporting should also be considered. Based on this study, risk of myocarditis following SARS-CoV-2 vaccination may be more serious than that reported previously."

[782] **ADDED since 2/8/2022**

Apparent risks of postural orthostatic tachycardia syndrome diagnoses after COVID-19 vaccination and SARS-Cov-2 Infection

Nature Cardiovascular Research — Cedars-Sinai Medical Center, Los Angeles

Alan C. Kwan, Joseph E. Ebinger, *et al*.

December 12, 2022

https://www.nature.com/articles/s44161-022-00177-8

"**Abstract**: Postural orthostatic tachycardia syndrome (POTS) was previously described after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection; however, limited data are available on the relation of POTS with Coronavirus Disease 2019 (COVID-19) vaccination. Here we show, in a cohort of 284,592 COVID-19-vaccinated individuals, using a

sequence–symmetry analysis, that the odds of POTS are higher 90 days after vaccine exposure than 90 days before exposure; we also show that the odds for POTS are higher than referent conventional primary care diagnoses but lower than the odds of new POTS diagnosis after SARS-CoV-2 infection."

[783] **ADDED since 2/8/2022**

Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination

Clinical Research in Cardiology — Heidelberg University Hospital, Heidelberg, Germany
Constantin Schwab, Lisa Marka Domke, *et al*.
November 27, 2022
https://link.springer.com/article/10.1007/s00392-022-02129-5

"**Introduction**: … Recently, unusual cases of (epi-)myocarditis after vaccination with mRNA-based anti-SARS-CoV-2-vaccines have been documented. These were clinically observed and diagnosed by laboratory and cardiac magnetic resonance imaging, predominantly in males under 30 years of age…

Here, we describe the cardiac autopsy findings in five persons who have died unexpectedly within seven days following anti-SARS-CoV-2-vaccination, with vaccine-induced myocardial inflammation representing the likely or possible cause of death. Our findings establish the histological phenotype of **lethal vaccination-associated myocarditis**…

Results: … Four persons died after the first vaccine jab, the remaining case after the second dose. All persons died within the first week following vaccination (mean 2.5 days, median 2 days)…

All cases lacked significant coronary heart disease, acute or chronic manifestations of ischaemic heart disease, manifestations of cardiomyopathy or **other signs of a pre-existing, clinically relevant heart disease**.

Discussion: In general, a **causal link between myocarditis and anti-SARS-CoV-2 vaccination** is supported by several considerations: (A) a close temporal relation to vaccination; all cases were found dead within one week after vaccination, (B) absence of any other significant pre-existing heart disease, especially ischaemic heart disease or cardiomyopathy, (C) negative testing for potential myocarditis-causing infectious agents, (D) presence of a peculiar CD4 predominant T-cell infiltrate, suggesting an immune mediated mechanism."

[784] **ADDED since 2/8/2022**

Video (4m): *Until Proven Otherwise – Two of the Top Cardiologists in the World*

Featuring cardiologists Dr. Peter McCullough and Dr. Aseem Malhotra
November 4, 2022
https://rumble.com/v1rl1kk-until-proven-otherwise-featuring-cardiologists-dr.-peter-mccullough-dr.-ase.html

Malhotra: "It is my duty and responsibility, as a consultant cardiologist and public-health campaigner, to urgently inform doctors, patients, and members of the public that the COVID mRNA vaccine has likely played a significant role or been a primary cause of unexpected cardiac arrests, heart attacks, strokes, cardiac arrhythmias, and heart failure since 2021 —

until proven otherwise."

McCullough: "200 papers showing that the myocarditis causes heart damage and a scar, and then the scar becomes the basis for a cardiac arrhythmia, and then the arrhythmia is responsible for the sudden death that we're seeing. And we're seeing sudden death now on a massive scale in younger people. It's my view **it's the COVID-19 vaccine** until proven otherwise."

[785] **ADDED since 2/8/2022**

A postmortem study of patients vaccinated for SARS-CoV-2 in Colombia

Spanish Journal of Pathology — Hospital San José, Colombia
Juan Jose Chaves, Juan Carlos Bonilla, *et al*.
October 31, 2022
https://www.sciencedirect.com/science/article/pii/S1699885522000642

"**Materials and methods**: A descriptive cross-sectional study of 121 autopsies was performed following Colombian regulations in two main hospitals in Bogotá, Colombia, between March 1st and April 31st, 2021.

Results: 118 of the 121 patients (97.52%) had been vaccinated with CoronaVac (Sinovac); only 3 had received other vaccines…

SCD [*sudden cardiac death*] was the leading cause of death with **69 cases (57.02%)**, followed by acute myocardial infarction in **53 patients (43.8%)** and other cardiovascular diseases (aortic dissection, aortic aneurysms, arrhythmias) in 23 patients (19%). 45 of the SCD cases were secondary to acute myocardial infarction and a further 18 cases secondary to other cardiovascular diseases. In 6 cases of SCD no diagnostic findings were found. Pulmonary embolism (PE) was found in 25 cases (20.66%)."

[786] **ADDED since 2/8/2022**

Significant incidence of myocarditis after 3rd dose of COVID-19 messenger RNA vaccine

Cardio Online
Guillaume Le Pessec
October 24, 2022
https://www.cardio-online.fr/Actualites/A-la-une/ESC-2022/Incidence-non-negligeable-myocardites-apres-3-dose-vaccin-ARN-messager-anti-COVID-19

"Based on the presentation by Christian Eugen Mueller (Basel, Switzerland): 'Myocardial Inflammation/Myocarditis After COVID-19 mRNA Booster Vaccination'

Methodology and results: A total of 835 patients were enrolled, of which 777 received troponinemia assay on Day 3, of these patients 40 had increased troponinemia. In 18 of them it was identified causes other than the vaccine that could explain the elevation of troponinemia, and in the remaining 22 no other cause than the vaccine was implicated. The study population was predominantly composed of women (69%), the average age was 37 years and patients received their 3Th dose 92%. Less than 2% had a history of cardiovascular disease.

The results of the study found that **2.8%** of the vaccinated population had myocardial lesions, 3.7% in women and 0.8% in men (Figure 1)."

[787] **ADDED since 2/8/2022**

State Surgeon General Dr. Joseph A. Ladapo Issues New mRNA COVID-19 Vaccine Guidance

Florida Department of Health
October 7, 2022
https://content.govdelivery.com/accounts/FLDOH/bulletins/3312697

> "Today, State Surgeon General Dr. Joseph A. Ladapo has announced new guidance regarding mRNA vaccines. The Florida Department of Health (Department) conducted an analysis through a self-controlled case series, which is a technique originally developed to evaluate vaccine safety.
>
> This analysis found that there is an **84% increase in the relative incidence of cardiac-related death** among males 18-39 years old within 28 days following mRNA vaccination. With a high level of global immunity to COVID-19, the benefit of vaccination is likely outweighed by this abnormally high risk of cardiac-related death among men in this age group. Non-mRNA vaccines were not found to have these increased risks.
>
> As such, the State Surgeon General recommends against males aged 18 to 39 from receiving mRNA COVID-19 vaccines."

[788] **ADDED since 2/8/2022**

Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States

Annals of Internal Medicine — Kaiser Permanente Northern California
Kristin Goddard, Kayla E. Hanson, *et al*.
October 4, 2022
https://www.acpjournals.org/doi/10.7326/M22-2274

> "**Background**: Vaccine safety monitoring systems worldwide have reported cases of myocarditis/pericarditis after mRNA-based COVID-19 vaccines (Pfizer-BioNTech and Moderna), especially among younger male persons 0 to 7 days after they received dose 2. Less is known about the incidence of myocarditis/pericarditis after booster doses.
>
> **Objective**: To estimate the incidence of myocarditis/pericarditis during days 0 to 7 after mRNA vaccination by age, sex, dose number, and product…
>
> **Discussion**: In this population-based surveillance, we found that myocarditis/pericarditis 0 to 7 days after mRNA vaccination in persons aged 5 to 39 years occurred in approximately 1 in 200 000 doses after the first dose and 1 in 30 000 doses after second dose of the primary series, and 1 in 50 000 doses after the first booster. The incidence varied markedly by age and sex, however, with a disproportionate number of cases occurring in male persons, notably among adolescents after dose 2 and first boosters."

Table. Incidence Rate of Verified Myocarditis/Pericarditis in the 0 to 7 Days After mRNA COVID-19 Vaccination Among Persons Aged 5 to 39 Years by Product, Age Group, Sex, and Dose Number*

Product and Patient Group	Dose 1		Dose 2		First Booster	
	Cases/Doses Administered†	Incidence Rate/ Million Doses (95% CI)	Cases/Doses Administered†	Incidence Rate/ Million Doses (95% CI)	Cases/Doses Administered†	Incidence Rate/ Million Doses (95% CI)
Pfizer‡						
Male						
5-11 y	0/221 975	0.0 (0.0-13.5)	3/207 958	14.4 (3.0-42.2)	0/50 415	0.0 (0.0-59.4)
12-15 y§	2/212 977	9.39 (1.1-33.9)	31/205 955	150.5 (102.3-213.6)	5/81 613	61.3 (19.9-143.0)
16-17 y	1/105 147	9.51 (0.2-53.0)	14/102 091	137.1 (75.0-230.1)	9/47 874	188.0 (86.0-356.9)
18-29 y	4/348 080	11.5 (3.1-29.4)	27/331 889	81.4 (53.6-118.4)	7/166 973	41.9 (16.9-86.4)
30-39 y	1/352 403	2.8 (0.1-15.8)	5/341 527	14.6 (4.8-34.2)	3/197 554	15.2 (3.1-44.4)
Female						
5-11 y	0/215 986	0.0 (0.0-13.9)	0/202 596	0.0 (0.0-14.8)	0/49 261	0.0 (0.0-60.8)
12-15 y	0/210 741	0.0 (0.0-14.2)	5/204 074	24.5 (8.0-57.2)	0/84 114	0.0 (0.0-35.6)
16-17 y	1/110 066	9.1 (0.2-50.6)	1/107 173	9.3 (0.2-52.0)	2/55 004	36.4 (4.4-131.3)
18-29 y	1/414 730	2.4 (0.1-13.4)	2/400 321	5.0 (0.6-18.0)	1/240 226	4.2 (0.1-23.2)
30-39 y	0/420 934	0.0 (0.0-7.1)	3/410 713	7.3 (1.5-21.3)	1/268 412	3.7 (0.1-20.8)
Moderna‖¶						
Male						
18-29 y	5/207 073	24.2 (7.8-56.3)	19/195 809	97.0 (58.4-151.5)	7/109 337	64.0 (25.7-131.9)
30-39 y	1/223 064	4.5 (0.1-25.0)	8/216 583	36.9 (15.9-72.8)	1/149 468	6.7 (0.2-37.3)
Female						
18-29 y	1/253 773	3.9 (0.1-22.0)	0/243 560	0.0 (0.0-12.3)	1/156 707	6.4 (0.2-35.6)
30-39 y	1/265 362	3.8 (0.1-21.0)	1/259 780	3.9 (0.1-21.4)	2/191 765	10.4 (1.3-37.7)

[789] **ADDED since 2/8/2022**

Video (6m): *Interview with Dr. Marty Makary*

Fox News

Tucker Carlson with Marth Makary, Johns Hopkins University

September 22, 2022

https://rumble.com/v1l8ju1-tucker-carlson-tonight-thursday-september-22.html

Makary: "Well, they famously downplayed [*the risk of myocarditis in children*]. The CDC director last year, said if we vaccinate a million children, there might be 30 or 40 cases of mild myocarditis. And they said, if you get myocarditis from COVID, that's worse or happens at a higher rate.

But that's not true. The studies have come out. Europe reacted by banning the Moderna vaccine altogether in young people, in many parts of Europe and everybody under 30, and in other places, everybody under 40.

The tragedy that we're now learning that there's **significant heart damage**, **31%** of people having physical activity restrictions. The Seattle study that **63%** of children after myocarditis had evidence of heart swelling months down the road on MRI.

So we were playing with fire. We didn't know what we were dealing with. They undercounted the complication rate, making the vaccine look safer than it really was, overcounting cases in young people, in hospitalizations, making the COVID infection look more dangerous than it really was.

And the tragedy is that we could have saved children from myocarditis. We could have protected this nation's children from myocarditis…

And we could have been honest about the risk [*of COVID to children*}. In healthy children, that risk is so low, it's lower than the risk of the vaccine."

[790] **ADDED since 2/8/2022**

Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex

Circulation — University of Oxford
Martina Patone, Xue W. Mei, *et al*.
September 6, 2022
https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.122.059970

"**Methods**: A self-controlled case series study of people ages 13 years or older vaccinated for COVID-19 in England between December 1, 2020, and December 15, 2021, evaluated the association between vaccination and myocarditis, stratified by age and sex. The incidence rate ratio and excess number of hospital admissions or deaths from myocarditis per million people were estimated for the 1 to 28 days after sequential doses of adenovirus (ChAdOx1) or mRNA-based (BNT162b2, mRNA-1273) vaccines, or after a positive SARS-CoV-2 test.

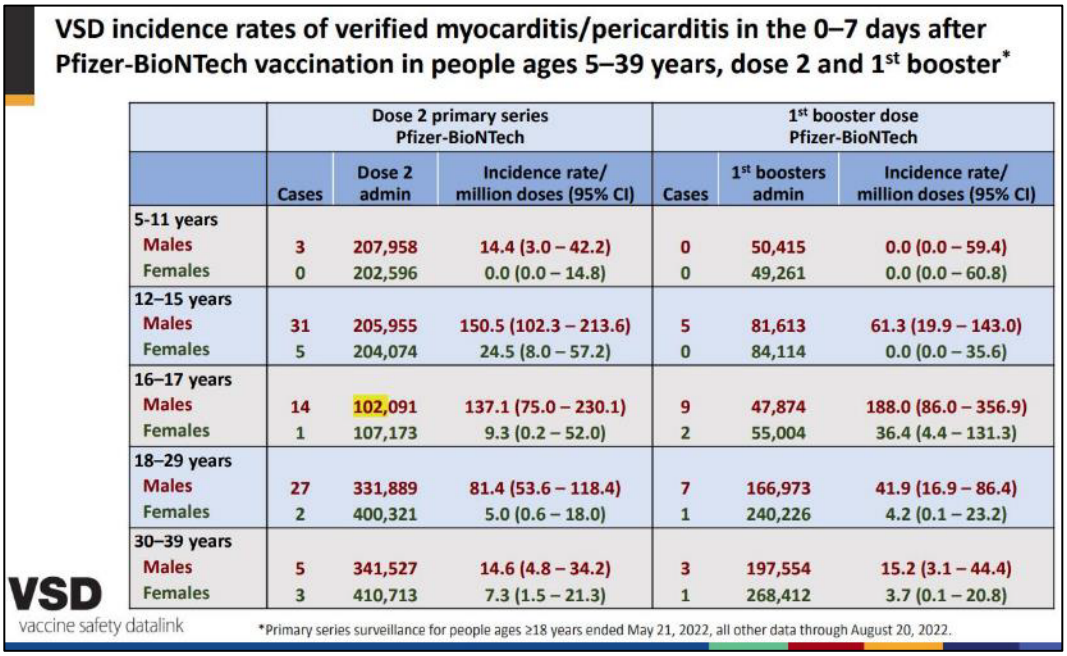
Results: … The risk of myocarditis was higher 1 to 28 days after a second dose of mRNA-1273 (11.76 [95% CI, 7.25–19.08]) and persisted after a booster dose (2.64 [95% CI, 1.25–5.58]). Associations were stronger in men younger than 40 years for all vaccines. In men younger than 40 years old, the number of excess myocarditis events per million people was higher after a second dose of mRNA-1273 than after a positive SARS-CoV-2 test (**97** [95% CI, 91–99] versus **16** [95% CI, 12–18]). In women younger than 40 years, the number of excess events per million was similar after a second dose of mRNA-1273 and a positive test (7 [95% CI, 1–9] versus 8 [95% CI, 6–8]).

Vaccine-Associated Myocarditis: In the study period, we observed 140 and 90 patients who were admitted to the hospital or died of myocarditis after a first and second dose of ChAdOx1 vaccine, respectively. Of these, 40 (28.6%) and 11 (12.2%), respectively, **died with myocarditis** or within 28 days from hospital admission. Similarly, there were 124, 119, and 85 patients who were admitted to the hospital or died of myocarditis after a first, second, and third dose of BNT162b2 vaccine, respectively. Of these, 22 (17.7%), 14 (11.8%), and 13 (15.3%) patients **died with myocarditis** or within 28 days from hospital admission."

[791] **ADDED since 2/8/2022**

COVID-19 vaccine safety update: Primary series in young children and booster doses in older children and adults

Centers for Disease Control and Prevention
Advisory Committee on Immunization Practices (ACIP)
Tom Shimabukuro, MD, MPH, MBA
September 1, 2022
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-09-01/05-COVID-Shimabukuro-508.pdf



VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days after Pfizer-BioNTech vaccination in people ages 5–39 years, dose 2 and 1st booster*

	Dose 2 primary series Pfizer-BioNTech			1st booster dose Pfizer-BioNTech		
	Cases	Dose 2 admin	Incidence rate/ million doses (95% CI)	Cases	1st boosters admin	Incidence rate/ million doses (95% CI)
5-11 years						
Males	3	207,958	14.4 (3.0 – 42.2)	0	50,415	0.0 (0.0 – 59.4)
Females	0	202,596	0.0 (0.0 – 14.8)	0	49,261	0.0 (0.0 – 60.8)
12–15 years						
Males	31	205,955	150.5 (102.3 – 213.6)	5	81,613	61.3 (19.9 – 143.0)
Females	5	204,074	24.5 (8.0 – 57.2)	0	84,114	0.0 (0.0 – 35.6)
16–17 years						
Males	14	102,091	137.1 (75.0 – 230.1)	9	47,874	188.0 (86.0 – 356.9)
Females	1	107,173	9.3 (0.2 – 52.0)	2	55,004	36.4 (4.4 – 131.3)
18–29 years						
Males	27	331,889	81.4 (53.6 – 118.4)	7	166,973	41.9 (16.9 – 86.4)
Females	2	400,321	5.0 (0.6 – 18.0)	1	240,226	4.2 (0.1 – 23.2)
30–39 years						
Males	5	341,527	14.6 (4.8 – 34.2)	3	197,554	15.2 (3.1 – 44.4)
Females	3	410,713	7.3 (1.5 – 21.3)	1	268,412	3.7 (0.1 – 20.8)

VSD vaccine safety datalink

*Primary series surveillance for people ages ≥18 years ended May 21, 2022, all other data through August 20, 2022.

[792] **ADDED since 2/8/2022**

Cardiovascular Effects of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents

Tropical Medicine and Infectious Disease — Mahidol University, Thailand
Suyanee Mansanguan, Prakaykaew Charunwatthana, *et al*.
August 19, 2022
https://www.mdpi.com/2414-6366/7/8/196

"**Abstract**: This study focuses on cardiovascular manifestation, particularly myocarditis and pericarditis events, after BNT162b2 mRNA COVID-19 vaccine injection in Thai adolescents. This prospective cohort study enrolled students aged 13–18 years from two schools, who received the second dose of the BNT162b2 mRNA COVID-19 vaccine. Data including demographics, symptoms, vital signs, ECG, echocardiography, and cardiac enzymes were collected at baseline, Day 3, Day 7, and Day 14 (optional) using case record forms. We enrolled 314 participants; of these, 13 participants were lost to follow-up, leaving 301 participants for analysis. The most common cardiovascular signs and symptoms were tachycardia (7.64%), shortness of breath (6.64%), palpitation (4.32%), chest pain (4.32%), and hypertension (3.99%). One participant could have more than one sign and/or symptom. Seven participants (2.33%) exhibited at least one elevated cardiac biomarker or positive lab assessments. **Cardiovascular manifestations were found in 29.24% of patients**, ranging from tachycardia or palpitation to myopericarditis…

3.4. Evaluation of Patients Developing Abnormal ECG Post-Vaccination

After vaccination, ECG revealed that of the 301 patients, 247 (82.06%) had normal sinus rhythm, while an **abnormal ECG finding was noted in 54 patients (17.94%)** (Table 4). The most common abnormal ECG finding was sinus rhythm with sinus arrhythmia (7.31%), followed by sinus tachycardia (6.64%) and sinus bradycardia (1.33%)."

[793] **ADDED since 2/8/2022**

Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents

Tropical Medicine and Infectious Disease — Mahidol University, Thailand

Suyanee Mansanguan,1 Prakaykaew Charunwatthana, *et al*.

August 7, 2022

https://www.mdpi.com/2414-6366/7/8/196

"**Abstract**: This study focuses on cardiovascular manifestation, particularly myocarditis and pericarditis events, after BNT162b2 mRNA COVID-19 vaccine injection in Thai adolescents. This prospective cohort study enrolled students aged 13–18 years from two schools, who received the second dose of the BNT162b2 mRNA COVID-19 vaccine…We enrolled 314 participants; of these, 13 participants were lost to follow-up, leaving 301 participants for analysis. The most common cardiovascular signs and symptoms were tachycardia (7.64%), shortness of breath (6.64%), palpitation (4.32%), chest pain (4.32%), and hypertension (3.99%). One participant could have more than one sign and/or symptom. Seven participants (2.33%) exhibited at least one elevated cardiac biomarker or positive lab assessments. **Cardiovascular manifestations were found in 29.24% of patients**, ranging from tachycardia or palpitation to myopericarditis."

[794] **ADDED since 2/8/2022**

Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines

Nature Communications — French National Agency for the Safety of Medicines and Health Products

Stéphane Le Vu, Marion Bertrand, *et al*.

June 25, 2022

https://www.nature.com/articles/s41467-022-31401-5

"Cases of myocarditis and pericarditis have been reported following the receipt of Covid-19 mRNA vaccines. As vaccination campaigns are still to be extended, we aimed to provide a comprehensive assessment of the association, by vaccine and across sex and age groups. Using nationwide hospital discharge and vaccine data, we analysed all 1612 cases of myocarditis and 1613 cases of pericarditis that occurred in France in the period from May 12, 2021 to October 31, 2021. We perform matched case-control studies and find **increased risks of myocarditis and pericarditis during the first week following vaccination**, and **particularly after the second dose**, with adjusted odds ratios of myocarditis of **8.1** (95% confidence interval [CI], 6.7 to 9.9) for the BNT162b2 and **30** (95% CI, 21 to 43) for the mRNA-1273 vaccine. The largest associations are observed for myocarditis following mRNA-1273 vaccination in persons aged 18 to 24 years. Estimates of excess cases attributable to vaccination also reveal a substantial burden of both myocarditis and pericarditis across other age groups and in both males and females."

[795] **ADDED since 2/8/2022**

Epidemiology of Myocarditis and Pericarditis Following mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents and Adults in Ontario, Canada

JAMA Network Open — Public Health Ontario
Sarah A. Buchan, Chi Yon Seo, *et al*.
June 24, 2022
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793551

"**Importance**: Increased rates of myocarditis or pericarditis following receipt of COVID-19 mRNA vaccines have been observed. However, few available data are associated with differences in rates of myocarditis or pericarditis specific to vaccine products, which may have important implications for vaccination programs…

Results: Among 19 740 741 doses of mRNA vaccines administered, there were 297 reports of myocarditis or pericarditis meeting the inclusion criteria; 228 (76.8%) occurred in male individuals, and the median age of individuals with a reported event was 24 years (range, 12-81 years). Of the reported cases, 207 (69.7%) occurred following the second dose of the COVID-19 mRNA vaccine. When restricted to individuals who received their second dose during the period of enhanced passive surveillance (on or after June 1, 2021), the highest rate of myocarditis or pericarditis was observed in male individuals aged 18 to 24 years following mRNA-1273 as the second dose (**299.5 cases per 1 000 000 doses**; 95% CI, 171.2-486.4 cases per 1 000 000 doses); the rate following BNT162b2 as the second dose was **59.2 cases per 1 000 000 doses** (95% CI, 19.2-138.1 cases per 1 000 000 doses). Overall rates for both vaccine products were significantly higher when the interdose interval was 30 or fewer days (BNT162b2: 52.1 cases per 1 000 000 doses [95% CI, 31.8-80.5 cases per 1 000 000 doses]; mRNA-1273: 83.9 cases per 1 000 000 doses [95% CI, 47.0-138.4 cases per 1 000 000 doses]) compared with 56 or more days (BNT162b2: 9.6 cases per 1 000 000 doses [95% CI, 6.5-13.6 cases per 1 000 000 doses]; mRNA-1273: 16.2 cases per 1 000 000 doses [95% CI, 10.2-24.6 cases per 1 000 000 doses])."

[796] **ADDED since 2/8/2022**

Intramyocardial Inflammation after COVID-19 Vaccination: An Endomyocardial Biopsy-Proven Case Series

International Journal of Molecular Scients — Institute of Cardiac Diagnostics and Therapy, Germany
Christian Baumeier, Ganna Aleshcheva, *et al*.
June 22, 2022
https://www.mdpi.com/1422-0067/23/13/6940

"**Abstract**: Myocarditis in response to COVID-19 vaccination has been reported since early 2021. In particular, young male individuals have been identified to exhibit an increased risk of myocardial inflammation following the administration of mRNA-based vaccines. Even though the first epidemiological analyses and numerous case reports investigated potential relationships, endomyocardial biopsy (EMB)-proven cases are limited. Here, we present a comprehensive histopathological analysis of EMBs from 15 patients with reduced ejection fraction (LVEF = 30 (14–39)%) and the clinical suspicion of myocarditis following vaccination with Comirnaty® (Pfizer-BioNTech) (n = 11), Vaxzevria® (AstraZenica) (n = 2) and Janssen® (Johnson & Johnson) (n = 2). Immunohistochemical EMB analyses reveal myocardial

inflammation in 14 of 15 patients, with the histopathological diagnosis of active myocarditis according the Dallas criteria (n = 2), severe giant cell myocarditis (n = 2) and inflammatory cardiomyopathy (n = 10). Importantly, infectious causes have been excluded in all patients. The SARS-CoV-2 spike protein has been detected sparsely on cardiomyocytes of nine patients, and differential analysis of inflammatory markers such as CD4+ and CD8+ T cells suggests that the inflammatory response triggered by the vaccine may be of autoimmunological origin. Although a definitive causal relationship between COVID-19 vaccination and the occurrence of myocardial inflammation cannot be demonstrated in this study, data suggest a temporal connection. The **expression of SARS-CoV-2 spike protein within the heart** and the dominance of CD4+ lymphocytic infiltrates indicate an autoimmunological response to the vaccination."

[797] **ADDED since 2/8/2022**

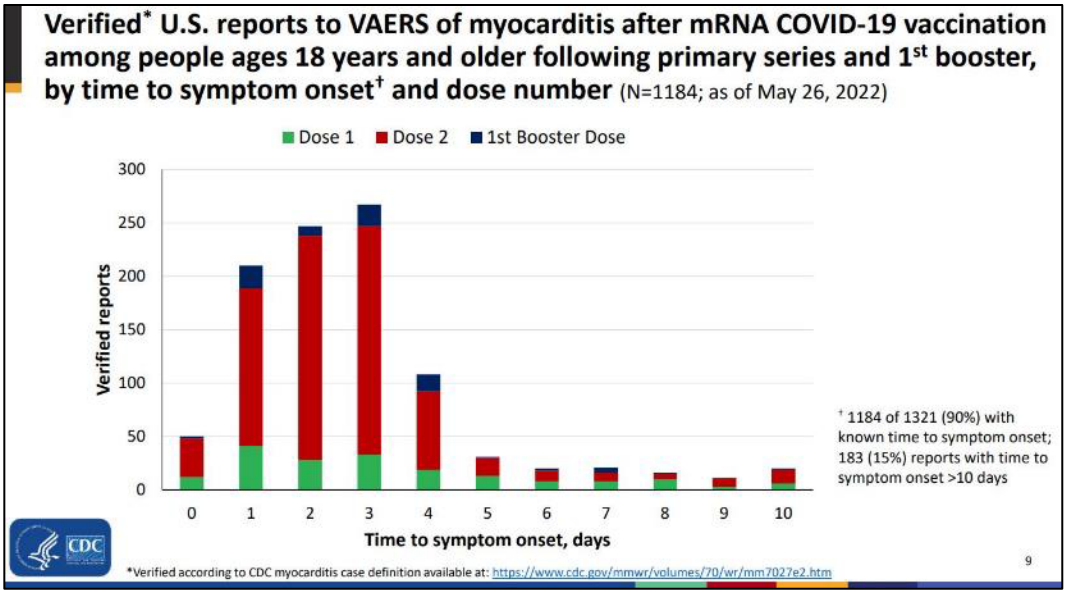
Update on myocarditis following mRNA COVID-19 vaccination
Centers for Disease Control and Prevention
Vaccines and Related Biological Products Advisory Committee (VRBPAC)
Tom Shimabukuro, MD, MPH, MBA
June 7, 2022
https://www.fda.gov/media/159007/download

Slide 8: "U.S. reports to VAERS of myocarditis after mRNA COVID-19 vaccination among people ages 18 years and older following primary series and 1st booster (as of May 26, 2022)

Preliminary reports of myocarditis (N=1836)

Met CDC definition (N=**1321**)

Slide 9:



[798] **ADDED since 2/8/2022**

Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave

Nature Scientific Reports
Christopher L. F. Sun, Eli Jaffe & Retsef Levi
April 28, 2022
https://www.nature.com/articles/s41598-022-10928-z

"**Discussion**: This study leverages a unique dataset of all EMS CA [*cardiac arrest*] and ACS [*acute coronary syndrome*] calls in Israel over two and half years that span 14 months prior to the start of the COVID-19 pandemic, 10 months that include two waves of the COVID-19 pandemic, and 6 months with a third wave of the pandemic parallel to the vaccination rollout among the 16-year-old and over population. Thus, it provides a unique perspective to explore the association between trends in CA and ACS call volume over the study period and different factors, such as COVID-19 infection rates and vaccination rates…

The main finding of this study concerns with **increases of over 25% in both the number of CA calls and ACS calls of people in the 16–39 age group during the COVID-19 vaccination rollout in Israel (January–May, 2021), compared with the same period of time in prior years (2019 and 2020)**, as shown in Table 1. Moreover, there is a robust and statistically significant association between the weekly CA and ACS call counts, and the rates of 1st and 2nd vaccine doses administered to this age group. At the same time there is no observed statistically significant association between COVID-19 infection rates and the CA and ACS call counts. This result is aligned with previous findings which show increases in overall CA incidence were not always associated with higher COVID-19 infections rates at a population level, as well as the stability of hospitalization rates related to myocardial infarction throughout the initial COVID-19 wave compared to pre-pandemic baselines in Israel. These results also are mirrored by a report of increased emergency department visits with cardiovascular complaints during the vaccination rollout in Germany as well as increased EMS calls for cardiac incidents in Scotland."

[799] **ADDED since 2/8/2022**

SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents

JAMA Cardiology — Norwegian Institute of Public Health
Øystein Karlstad, Petteri Hovi, *et al*.
April 20, 2022
https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253

"**Question:** Is SARS-CoV-2 messenger RNA (mRNA) vaccination associated with risk of myocarditis?

Findings: In a cohort study of 23.1 million residents across 4 Nordic countries, risk of myocarditis after the first and second doses of SARS-CoV-2 mRNA vaccines was highest in young males aged 16 to 24 years after the second dose. For young males receiving 2 doses of the same vaccine, data were compatible with between 4 and 7 excess events in 28 days per 100 000 vaccinees after second-dose BNT162b2, and between 9 and 28 per 100 000 vaccinees after second-dose mRNA-1273."

[800] **ADDED since 2/8/2022**

The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients—A Large Population-Based Study

Journal of Clinical Medicine — Hebrew University of Jerusalem
Ortal Tuvali, Sagi Tshori, *et al*.
April 15, 2022
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9025013/

"**Abstract**: We aimed to study the incidence of post-acute COVID-19 myocarditis and pericarditis. Retrospective cohort study of 196,992 adults after COVID-19 infection in Clalit Health Services members in Israel between March 2020 and January 2021… We did not observe an increased incidence of neither pericarditis nor myocarditis in adult patients recovering from COVID-19 infection…

Conclusions: Our data suggest that there is **no increase in the incidence** of myocarditis and pericarditis in COVID-19 recovered patients compared to uninfected matched controls."

[801] **ADDED since 2/8/2022**

Risk of myopericarditis following COVID-19 mRNA vaccination in a large integrated health system: A comparison of completeness and timeliness of two methods

Pharmacoepidemiology & Drug Safety — Kaiser Permanente Northwest
Katie A. Sharff, David M. Dancoes, Jodi L. Longueil, Eric S. Johson, and Paul F. Lewis
April 11, 2022
https://onlinelibrary.wiley.com/doi/10.1002/pds.5439

"**Methods**: We assembled a cohort 12–39 year-old patients, insured by Kaiser Permanente Northwest, who received at least one dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) between December 2020 and October 2021. We followed them for up to 30 days after their second dose of an mRNA vaccine to identify encounters for myocarditis, pericarditis or myopericarditis…

Results: … Among those who received a second dose of vaccine (n = 146 785), we estimated a risk as **95.4 cases of myopericarditis per million second doses administered** (95% CI, 52.1–160.0).

Conclusion: We identified additional valid cases of myopericarditis following an mRNA vaccination that would be missed by the VSD's [*Vaccine Safety Datalink*] search algorithm, which depends on select hospital discharge diagnosis codes. The **true incidence of myopericarditis is markedly higher** than the incidence reported to US advisory committees in the fall of 2021. The VSD should validate its search algorithm to improve its sensitivity for myopericarditis."

[802] **ADDED since 2/8/2022**

Epidemiology, clinical ramifications, and cellular pathogenesis of COVID-19 mRNA-vaccination-induced adverse cardiovascular outcomes: A state-of-the-heart review

Biomedicine & Pharmacotherapy — Royal College of Surgeons, Ireland
Talal Almas, Sarah Rehman, *et al*.
March 21, 2022
https://www.sciencedirect.com/science/article/pii/S0753332222002311

"**Abstract**: … [M]any side-effects are being reported after COVID-19 vaccinations and **myocarditis** is the most commonly reported sequelae post vaccination. Majority of these diseases are associated with COVID-19 mRNA vaccines. Various studies have established a temporal relationship between these complications, yet the causality and the underlying pathogenesis remain hypothetical. In this review, we aim to critically appraise the available literature regarding the cardiovascular side effects of the various mRNA vaccines and the associated pathophysiology…

3.1. Pathophysiology: … **The immunological response induced by the vaccines could explain the inflammatory processes of myocarditis, pericarditis, and perimyocarditis**. As briefly mentioned earlier, MI induced by the vaccines could be attributed to Kounis syndrome, which is largely explained by components within the vaccines known as **excipients** [11]. Excipients are pharmaceutical substances found alongside the active substances in a vaccine. In this case, the COVID-19 vaccine excipients are speculated to be potentially eliciting hypersensitivity reactions amongst some recipients.

Summary: To summarize, several studies reporting cases of cardiovascular side effects secondary to mRNA COVID-19 vaccines have been discussed. These include **myocarditis**, **perimyocarditis**, **pericarditis**, **MIs**, and **Takotsubo syndrome** [21], [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32]. Most pertinently, the time between vaccination and the onset of symptoms varied between complications. The reported cases shared certain predisposing risk factors, such as hypertension, active smoking and a previous history of CAD [14], [15], [16], [17], [18], [19], [20], [21]. The reported cases were mainly males with age variation. Notably, myocarditis predominantly affected younger males while pericarditis was observed in older males [24], [27]. While myocarditis is the highest reported cardiovascular ramification, other serious complications are also being increasingly reported [3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [27], [31], [32], [33]."

[803] **ADDED since 2/8/2022**

Autopsy Histopathologic Cardiac Findings in 2 Adolescents Following the Second COVID-19 Vaccine Dose

Archives of Pathology & Laboratory Medicine
James R. Gill, Randy Tashjian, and Emily Duncanson
February 14, 2022
https://meridian.allenpress.com/aplm/article/146/8/925/477788/Autopsy-Histopathologic-Cardiac-Findings-in-2

"**Context**: Myocarditis in adolescents has been diagnosed clinically following the administration of the second dose of an mRNA vaccine for coronavirus disease 2019 (COVID-19).

Objective: To examine the autopsy microscopic cardiac findings in adolescent deaths that occurred shortly following administration of the second Pfizer-BioNTech COVID-19 dose to determine if the myocarditis described in these instances has the typical histopathology of myocarditis.

Results: The microscopic examination revealed features resembling a catecholamine-induced injury, not typical myocarditis pathology.

Conclusions: The myocardial injury seen in these postvaccine hearts is different from typical myocarditis and **has an appearance most closely resembling a catecholamine-mediated stress (toxic) cardiomyopathy**.

Discussion: … **Toxic myocarditis** is an etiologic classification involving **direct myocardial injury by various drugs or substances**. Although variable, the histologic features consist of 2 main patterns: an early stage with foci of solely necrotic/damaged myocytes and the later phase of 'myocarditis.' Toxic myocarditis usually indicates inflammatory stages of catecholamine-induced myocardial injury."

[804] **ADDED since 2/8/2022**

BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis

European Journal of Clinical Investigation
Allison Krug, Josh Stevenson, and Tracy Beth Høeg
February 14, 2022
https://onlinelibrary.wiley.com/doi/10.1111/eci.13759

"**Methods**: Using the Vaccine Adverse Event Reporting System (VAERS), we identified BNT162b2 [Pfizer-BioNTech] myo/pericarditis occurrence according to CDC criteria. Main outcomes were as follows: 1) post-vaccination myo/pericarditis crude incidence in adolescents aged 12–15 and 16–17; and 2) two risk-benefit analyses by age, sex, comorbidity, variant and history of infection.

Results: Cases of myo/pericarditis (n = 253) included 129 after dose 1 and 124 after dose 2; **86.9% were hospitalized**. Incidence per million after dose two in male patients aged 12–15 and 16–17 was 162.2 and 93.0, respectively. Weighing post-vaccination myo/pericarditis against COVID-19 hospitalization during delta, our risk-benefit analysis suggests that among 12–17-year-olds, two-dose vaccination was uniformly favourable only in nonimmune girls with a comorbidity. In boys with prior infection and no comorbidities, even one dose carried more risk than benefit according to international estimates. In the setting of omicron, one dose may be protective in nonimmune children, but dose two does not appear to confer additional benefit at a population level."

[805] **Video interview (17m): *Tawny Buettner, RN, observed a 10X increase in the rate of myocarditis after the vaccines rolled out***
Steve Kirsch
January 28, 2022
https://rumble.com/vtge32-tawny-buettner-rn-observed-a-10x-increase-in-the-rate-of-myocarditis-after-.html

Buettner: "I worked at the Cardiovascular Intensive Care Unit [*CVICU*] at a major children's hospital in [*San Diego*] California… I was told that I could no longer be in a patient-facing position as an unvaccinated employee… I was also a charge nurse…

Before COVID … we would see maybe four [*myocarditis cases*] a year, five a year… During COVID… we only had one patient cared for by the CVICU team that had an active COVID infection…

Kirsch: What happened after the vaccines rolled out?

Buettner: … After the vaccine, we saw a huge increase in myocarditis cases.

Kirsch: How many cases?

Buettner: I am aware of 33 cases that came in from the period of about June-ish until I was fired on October 1st…

What we saw coming in were children who were very active. They were playing sports, they were thin, they did not have health issues… before the vaccine.

Kirsch: Is there any doubt in your mind that the vaccine is causing this uptick in myocarditis?

Buettner: There's absolutely no doubt that the vaccine is causing myocarditis in children…

The hospital that I worked for… there is no policy on reporting to VAERS [*Vaccine Adverse Event Reporting System*]. So the doctors do not have a policy that requires them to report to VAERS, nor is there any sort of procedure on how to report to VAERS, so it is up to the discretion of the doctor of whether they report to VAERS or not…

I've talked to many pediatric nurses who have worked in childrens hospitals and there is no VAERS policy for doctors, clinicians, nurse practitioners, nurses; no policy for them to report."

[806] ***Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021***
Journal of the American Medical Association (JAMA)
Matthew E. Oster, David K. Shay, *et al*.
January 25, 2022
https://jamanetwork.com/journals/jama/fullarticle/2788346

"**Findings**: In this descriptive study of 1626 cases of myocarditis in a national passive reporting system, the crude reporting rates within 7 days after vaccination exceeded the expected rates across multiple age and sex strata. The rates of myocarditis cases were highest after the second vaccination dose in adolescent males aged 12 to 15 years (70.7 per million doses of the BNT162b2 vaccine), in adolescent males aged 16 to 17 years (105.9 per million doses of the BNT162b2 vaccine), and in young men aged 18 to 24 years (52.4 and 56.3 per million doses of the BNT162b2 vaccine and the mRNA-1273 vaccine, respectively).

Meaning: Based on passive surveillance reporting in the US, the risk of myocarditis after receiving mRNA-based COVID-19 vaccines was increased across multiple age and sex strata and was highest after the second vaccination dose in adolescent males and young men."

[807] **ADDED since 2/8/2022**

Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection

Nature Medicine — University of Oxford
Martina Patone, Xue W. Mei, *et al*.
December 14, 2021
https://www.nature.com/articles/s41591-021-01630-0

"**Abstract**: Although myocarditis and pericarditis were not observed as adverse events in coronavirus disease 2019 (COVID-19) vaccine trials, there have been numerous reports of suspected cases following vaccination in the general population. We undertook a self-controlled case series study of people aged 16 or older vaccinated for COVID-19 in England between 1 December 2020 and 24 August 2021 to investigate hospital admission or death from myocarditis, pericarditis and cardiac arrhythmias in the 1–28 days following adenovirus (ChAdOx1, n = 20,615,911) or messenger RNA-based (BNT162b2, n = 16,993,389; mRNA-1273, n = 1,006,191) vaccines or a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) positive test (n = 3,028,867). We found **increased risks of myocarditis** associated with the first dose of ChAdOx1 and BNT162b2 vaccines and the first and second doses of the mRNA-1273 vaccine over the 1–28 days postvaccination period, and after a SARS-CoV-2 positive test. We estimated an extra two (95% confidence interval (CI) 0, 3), one (95% CI 0, 2) and six (95% CI 2, 8) myocarditis events per 1 million people vaccinated with ChAdOx1, BNT162b2 and mRNA-1273, respectively, in the 28 days following a first dose and an extra ten (95% CI 7, 11) myocarditis events per 1 million vaccinated in the 28 days after a second dose of mRNA-1273. This compares with an extra 40 (95% CI 38, 41) myocarditis events per 1 million patients in the 28 days following a SARS-CoV-2 positive test."

[808] ***Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination***

Clinical Infectious Diseases (University of Hong Kong)
Gilbert T. Chua, Mike Yat Wah Kwan, *et al*.
November 28, 2021
https://academic.oup.com/cid/advance-article-abstract/doi/10.1093/cid/ciab989/6445179

"**Methods**: This is a population cohort study in Hong Kong that monitored adverse events following immunization through a pharmacovigilance system for COVID-19 vaccines. All adolescents aged between 12 and 17 years following Comirnaty vaccination were monitored under the COVID-19 vaccine Adverse Event Response and Evaluation Programme…

Results: … The overall incidence of acute myocarditis/pericarditis was 18.52 (95% Confidence Interval [CI], 11.67-29.01) per 100,000 persons vaccinated. The incidence after the first and second doses were 3.37 (95%CI 1.12-9.51) and 21.22 (95%CI 13.78-32.28) per 100,000 persons vaccinated, respectively. Among male adolescents, the incidence after the first and second doses were 5.57 (95% CI 2.38-12.53) and 37.32 (95% CI 26.98-51.25) per 100,000 persons vaccinated.

Conclusions: There is a significant increase in the risk of acute myocarditis/pericarditis following Comirnaty vaccination among Chinese male adolescents, especially after the second dose."

[809] ***Germany, France Restrict Moderna's Covid Vaccine For Under-30s Over Rare Heart Risk—Despite Surging Cases***
Forbes
Robert Hart
November 10, 2021
https://www.forbes.com/sites/roberthart/2021/11/10/germany-france-restrict-modernas-covid-vaccine-for-under-30s-over-rare-heart-risk-despite-surging-cases/

"Germany and France are the latest European countries to restrict the use of Moderna's Covid-19 vaccine in younger people, joining a string of Nordic nations including Finland, Sweden, Denmark and Norway. All cite studies indicating a very limited risk of heart inflammation in young recipients of mRNA coronavirus vaccines, which includes Pfizer and Moderna shots."

[810] ***Abstract 10712: Mrna COVID Vaccines Dramatically Increase Endothelial Inflammatory Markers and ACS Risk as Measured by the PULS Cardiac Test: a Warning***
Circulation
Dr. Steven R. Gundry, International Heart and Lung Institute
November 8, 2021
https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712

"**Abstract**: Our group has been using the PLUS Cardiac Test (GD Biosciences, Inc, Irvine, CA) a clinically validated measurement of multiple protein biomarkers which generates a score predicting the 5 yr risk (percentage chance) of a new Acute Coronary Syndrome (ACS). The score is based on changes from the norm of multiple protein biomarkers including IL-16, a proinflammatory cytokine, soluble Fas, an inducer of apoptosis, and Hepatocyte Growth Factor (HGF) which serves as a marker for chemotaxis of T-cells into epithelium and cardiac tissue, among other markers. Elevation above the norm increases the PULS score, while decreases below the norm lowers the PULS score. The score has been measured every 3-6 months in our patient population for 8 years. Recently, with the advent of the mRNA COVID 19 vaccines (vac) by Moderna and Pfizer, **dramatic changes in the PULS score became apparent in most patients**. This report summarizes those results. A total of 566 pts, aged 28 to 97, M:F ratio 1:1 seen in a preventive cardiology practice had a new PULS test drawn from 2 to 10 weeks following the 2nd COVID shot and was compared to the previous PULS score drawn 3 to 5 months previously pre- shot… These changes resulted in an **increase of the PULS score from 11% 5 yr ACS risk to 25% 5 yr ACS risk**. At the time of this report, these changes persist for at least 2.5 months post second dose of vac. We conclude that **the mRNA vacs dramatically increase inflammation on the endothelium** and **T cell infiltration of cardiac muscle** and may account for the observations of increased thrombosis, cardiomyopathy, and other vascular events following vaccination [*emphasis added*]."

[811] **ADDED since 2/8/2022**

Abstract 10712: Observational Findings of PULS Cardiac Test Findings for Inflammatory Markers in Patients Receiving mRNA Vaccines

Circulation — The International Heart and Lung Institute
Steven R. Gundry
November 8, 2021
https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712

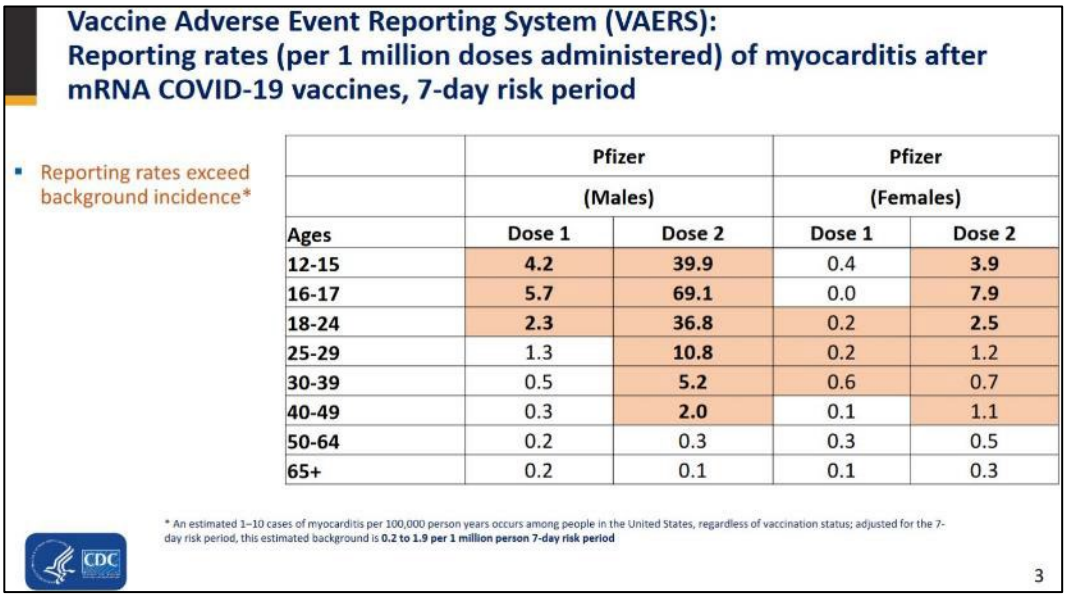
"**Abstract**: This clinic has been using the PULS Cardiac Test (Predictive Health Diagnostics Co., Irvine, CA) a clinically utilized measurement of multiple protein biomarkers, which generates a score predicting the 5 yr risk (percentage chance) of a new Acute Coronary Syndrome (ACS) called the PULS Score. The score is based on changes from the norm of multiple protein inflammatory biomarkers including IL-16, a proinflammatory cytokine, soluble Fas, an inducer of apoptosis, and Hepatocyte Growth Factor (HGF) which serves as a marker for chemotaxis of T-cells into epithelium and cardiac tissue, among other markers. Elevation above the norm increases the PULS score, while decreases below the norm lowers the PULS score. The PULS score has been measured every 3-6 months in our patient population for 8 years. Recently, with the advent of the mRNA COVID 19 vaccines (vac) by Moderna and Pfizer, we tracked the changes of the PULS score and three of the inflammatory markers it measures in all of our patients consecutively receiving these vaccines.

This report summarizes those results. A total of 566 pts, aged 28 to 97, M:F ratio 1:1 seen in a preventive cardiology practice had a previously scheduled PULS test drawn from 2 to 10 weeks following the 2nd mRNA COVID shot and was compared to the pt's PULS test drawn 3 to 5 months previously pre-shot…

Baseline IL-16 increased from 35+/-20 above the norm to 82 +/- 75 above the norm post-vac; sFas increased from 22+/- 15 above the norm to 46+/-24 above the norm post vac; HGF increased from 42+/-12 above the norm to 86+/-31 above the norm post vac. These changes resulted in an increase of the pre vac PULS score of predicted 11% 5 yr ACS risk to a post vac PULS score of a predicted 25% 5 yr ACS risk...

In conclusion, the **mRNA vacs numerically increase** (but not statistically tested) the markers IL-16, Fas, and HGF, all **markers** previously described by others **for denoting inflammation on the endothelium and T cell infiltration of cardiac muscle**, in a consecutive series of a single clinic patient population receiving mRNA vaccines without a control group."

[812] ***mRNA COVID-19 Vaccine-Associated Myocarditis***
Centers for Disease Control and Prevention
Mathew Oster
November 2, 2021
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/04-COVID-Oster-508.pdf



Vaccine Adverse Event Reporting System (VAERS): Reporting rates (per 1 million doses administered) of myocarditis after mRNA COVID-19 vaccines, 7-day risk period

- Reporting rates exceed background incidence*

	Pfizer (Males)		Pfizer (Females)	
Ages	Dose 1	Dose 2	Dose 1	Dose 2
12-15	**4.2**	**39.9**	0.4	**3.9**
16-17	**5.7**	**69.1**	0.0	**7.9**
18-24	**2.3**	**36.8**	0.2	**2.5**
25-29	1.3	**10.8**	0.2	1.2
30-39	0.5	**5.2**	0.6	0.7
40-49	0.3	**2.0**	0.1	1.1
50-64	0.2	0.3	0.3	0.5
65+	0.2	0.1	0.1	0.3

* An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for the 7-day risk period, this estimated background is **0.2 to 1.9 per 1 million person 7-day risk period**

3

[813] **ADDED since 2/8/2022**
Prospective Case-Control Study of Cardiovascular Abnormalities 6 Months Following Mild COVID-19 in Healthcare Workers
JACC: Cardiovascular Imaging — University College London
George Joy, Jessica Arico, *et al*.
November 1, 2021
https://www.sciencedirect.com/science/article/pii/S1936878X21003569

"**Objectives**: The purpose of this study was to detect cardiovascular changes after mild severe acute respiratory syndrome-coronavirus-2 infection.

Background: Concern exists that mild coronavirus disease 2019 may cause myocardial and vascular disease…

Conclusions: Cardiovascular abnormalities are **no more common** in seropositive versus seronegative otherwise healthy, workforce representative individuals **6 months post–mild severe acute respiratory syndrome-coronavirus-2 infection**."

[814] **ADDED since 2/8/2022**

Myopericarditis After the Pfizer Messenger Ribonucleic Acid Coronavirus Disease Vaccine in Adolescents

The Journal of Pediatrics — University of Washington
Jenna Schauer, Sujatha Buddhe, *et al*.
November 1, 2021
https://www.jpeds.com/article/S0022-3476(21)00665-X/fulltext

"Reports have emerged of myocarditis and pericarditis predominantly after the second dose of the coronavirus disease messenger ribonucleic acid vaccine. We describe **13 patients aged 12-17 years who presented with chest pain within 1 week after their second dose of the Pfizer vaccine** and were found to have elevated serum troponin levels and evidence of myopericarditis…

Discussion: We report 13 adolescents with myopericarditis after the second dose of the Pfizer mRNA COVID-19 vaccine. This cluster of cases was identifiable as the age of eligibility for vaccination broadened with Emergency Use Authorization by the Food and Drug Administration. Our hospital is the only freestanding children's hospital in Washington and serves as a tertiary referral institution. To our knowledge, at least 3 other cases in this age group have been cared for at other hospitals in the state. Using these numbers and Washington Department of Health data on immunization, we estimate a possible incidence of 0.008% in adolescents aged 16-17 years and 0.01% in those aged 12-15 years following the second dose.

All patients had evidence of myocardial inflammation and edema on CMR, similar to findings in limited case series of adults with post–COVID-19 vaccine myocarditis. Although the symptoms resolved rapidly in all patients, their CMR findings indicate the potential for myocardial fibrosis and unknown long-term impact."

[815] ***COVID-19 vaccine weekly safety report***

Department of Health (Australia)
October 28, 2021
https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-28-10-2021

"We are carefully monitoring and reviewing reports of:

- **myocarditis** and **pericarditis** following mRNA vaccines, particularly in younger age groups
- thrombosis with thrombocytopenia syndrome (TTS) following Vaxzevria (AstraZeneca)
- Guillain-Barre Syndrome (GBS) following Vaxzevria (AstraZeneca)
- immune thrombocytopenia (ITP) following Vaxzevria (AstraZeneca)"

[816] ***Sweden Public Health Agency Indefinitely Halts Use of Moderna mRNA-1273 on Young People 30 & Below***
TrialSiteNews
October 27, 2021
https://trialsitenews.com/sweden-publish-health-agency-indefinitely-halts-use-of-moderna-mrna-1273-on-young-people-30-below/

> "Sweden's Public Health Agency extended a moratorium indefinitely on the use of the Moderna mRNA-1293 vaccine to anyone age 30 and under… Heart inflammation in younger people is a known adverse effect associated with the Moderna vaccine, with young males facing higher risks…
>
> TrialSite reported that on October 6 Sweden halted the use of the mRNA COVID-19 vaccine on people under the age of 30 due to safety concerns. Just a couple of days later TrialSite shared with global audiences that **Iceland made the same move, along with the rest of the Scandinavian countries**, to either halt or in the case of Norway, discourage the use of the Moderna vaccine in younger people **due to the safety risks** [*emphasis added*]."

[817] **Briefing Document: *Vaccines and Related Biological Products Advisory Committee Meeting***
US Food and Drug Administration
October 26, 2021
https://www.fda.gov/media/153447/download

> "Post-EUA safety surveillance reports received by FDA and CDC identified increased risks of myocarditis and pericarditis, particularly within 7 days following administration of the second dose of the 2-dose primary series. Reporting rates for medical chart-confirmed myocarditis and pericarditis in VAERS have been higher among males under 40 years of age than among females and older males and have been highest in males 12 through 17 years of age (~71.5 cases per million second primary series doses among males age 16-17 years and 42.6 cases per million second primary series doses among males age 12-15 years as per CDC presentation to the ACIP on August 30, 2021). In an FDA analysis of the Optum healthcare claims database, the estimated excess risk of myocarditis/pericarditis approached **200 cases per million** fully vaccinated males 16-17 years of age and **180 cases per million** fully vaccinated males 12-15 years of age [*emphasis added*]."

[818] ***Use of Moderna's COVID-19 vaccine in Iceland***
Iceland Directorate of Health
October 8, 2021
https://www.landlaeknir.is/um-embaettid/frettir/frett/item47717/Notkun-COVID-19-boluefnis-Moderna-a-Islandi

> "In recent days, data from the Nordic countries on increased incidence of heart inflammation and gollum house inflammation after vaccination with Moderna vaccine have been presented…
>
> Since there is sufficient availability of Pfizer's vaccine in Iceland for both stimulation vaccinations of defined priority groups and the basic vaccinations of those who have not yet been vaccinated, **the quarantine officer has decided that Moderna vaccines will not be used in this country** while further information is obtained on the safety of Moderna's vaccine

[*emphasis added*] during stimulation vaccinations."

[819] ***A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products***
Current Problems in Cardiology
Jessica Rose and Peter McCullough
October 1, 2021
https://www.sciencedirect.com/science/article/pii/S0146280621002267

"**Abstract**: Following the global rollout and administration of the Pfizer Inc./BioNTech BNT162b2 and Moderna mRNA-1273 vaccines on December 17, 2020, in the United States, and of the Janssen Ad26.COV2.S product on April 1st, 2021, in an unprecedented manner, hundreds of thousands of individuals have reported adverse events (AEs) using the Vaccine Adverse Events Reports System (VAERS). We used VAERS data to examine cardiac AEs, primarily myocarditis, reported following injection of the first or second dose of the COVID-19 injectable products. Myocarditis rates reported in VAERS were significantly higher in youths between the ages of 13 to 23 ($p<0.0001$) with ~80% occurring in males. Within 8 weeks of the public offering of COVID-19 products to the 12-15-year-old age group, we found **19 times the expected number of myocarditis cases** in the vaccination volunteers over background myocarditis rates for this age group. In addition, a 5-fold increase in myocarditis rate was observed subsequent to dose 2 as opposed to dose 1 in 15-year-old males [*emphasis added*]. A total of 67% of all cases occurred with BNT162b2. Of the total myocarditis AE reports, 6 individuals died (1.1%) and of these, 2 were under 20 years of age - 1 was 13. These findings suggest a markedly higher risk for myocarditis subsequent to COVID-19 injectable product use than for other known vaccines, and this is well above known background rates for myocarditis. COVID-19 injectable products are novel and have a genetic, pathogenic mechanism of action causing uncontrolled expression of SARS-CoV-2 spike protein within human cells. When you combine this fact with the temporal relationship of AE occurrence and reporting, biological plausibility of cause and effect, and the fact that these data are internally and externally consistent with emerging sources of clinical data, it supports a conclusion that the COVID-19 biological products are deterministic for the myocarditis cases observed after injection."

[820] ***Heart inflammation rates higher after Moderna COVID-19 vaccine - Canada data***
Reuters
Manas Mishra
October 1, 2021
https://www.reuters.com/business/healthcare-pharmaceuticals/heart-inflammation-rates-higher-after-moderna-covid-19-shot-than-pfizer-vaccine-2021-10-01/

"Canadian health officials said on Friday data suggests reported cases of rare heart inflammation were relatively higher after Moderna's (MRNA.O) COVID-19 vaccine compared with the Pfizer/BioNTech shots….

The data also indicated heart inflammation occurs more often in adolescents and adults under 30 years of age, and more often in males."

[821] ***Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to August 7, 2021***
Public Health Ontario
September 2021
https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc_lang=en

"**Highlights**:

- Since the start of the COVID-19 immunization program in Ontario, there have been 314 reports of myocarditis or pericarditis following receipt of COVID-19 mRNA vaccines in Ontario…
- The highest reporting rate of myocarditis/pericarditis was observed in males aged 18-24 years following second dose. The reporting rate in this group following the Pfizer-BioNTech vaccine as second dose was **37.4 per million doses** and was **263.2 per million** following the Moderna vaccine as second dose [*emphasis added*]."

[822] ***Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting***
New England Journal of Medicine
Moam Barda, Moa Dagan, *et al*.
September 16, 2021
https://www.nejm.org/doi/10.1056/NEJMoa2110475

"**Results**: In the vaccination analysis, the vaccinated and control groups each included a mean of 884,828 persons. Vaccination was most strongly associated with an elevated risk of myocarditis…"

[823] ***Updated Signal assessment report on Myocarditis, pericarditis with Tozinameran (COVID-19 mRNA vaccine (nucleoside-modified) – COMIRNATY)***
European Medicines Agency (Pharmacovigilance Risk Assessment Committee)
September 2, 2021
https://www.ema.europa.eu/en/documents/prac-recommendation/updated-signal-assessment-report-myocarditis-pericarditis-tozinameran-covid-19-mrna-vaccine_en.pdf

"**1. Background**…

In Israel, a comparison of hospital admissions incidences rate due to myocarditis in vaccinees compared to non-vaccinees was performed in all ages groups, and the data suggested a potential signal with the vaccinees. There has not been a general comparison of hospitalizations by vaccine status.

The Israeli interim assessment was that there is a likely causal association between the **second dose of mRNA vaccine** (in Israel all cases were with Pfizer vaccine) and **myocarditis**. This association appears stronger in young males (16-19) as opposed to females and attenuates with increasing age. The numerical estimate is still being finalized, but is approximately between **1 In 10,000** to **1 in 6,000** second doses of vaccine [*emphasis added*]…

The Incidence rates for myocarditis only were obtained from IMRD UK (primary care healthcare records), noting the following. The myocarditis diagnosis is likely to be made in

secondary care, so there is a risk of underreporting in primary care records. Rates from ACCESS databases that include both primary and secondary care are for myocarditis and pericarditis combined, hence they couldn't be used…

The results showed an elevated OE [*observed/expected*] ratio (**> 5**) in the male 18-24 age group, **statistically significant** [*emphasis added*]."

[824] ***SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis***
medRxiv
Tracy Beth Hoeg, Allison Krug, *et al*.
August 30, 2021
https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1.full.pdf

"**Objectives**: Establishing the rate of post-vaccination cardiac myocarditis in the 12-15 and 16-17-year-old population in the context of their COVID-19 hospitalization risk is critical for developing a vaccination recommendation framework that balances harms with benefits for this patient demographic…

Results: … For boys 12-15 without medical comorbidities receiving their second mRNA vaccination dose, the **rate of CAE is 3.7 to 6.1 times higher** than their 120-day COVID-19 hospitalization risk as of August 21, 2021… For boys 16-17 without medical comorbidities, the **rate of CAE is currently 2.1 to 3.5 times higher** than their 120-day COVID-19 hospitalization risk. [*emphasis added*]…

Principal findings: The main finding of this study was the cardiac adverse event (CAE) rates of 162/million and 94/million post- Pfizer-BioNTech BNT162b2 vaccination dose two for the 12-15- and 16–17-year-old boys, respectively. Approximately **86% of these resulted in hospitalization** for both age groups [*emphasis added*]...

Conclusions: Post-vaccination CAE rate was highest in young boys aged 12-15 following dose two. For boys 12-17 without medical comorbidities, the likelihood of post vaccination dose two CAE is 162.2 and 94.0/million respectively. This incidence exceeds their expected 120-day COVID-19 hospitalization rate at both moderate (August 21, 2021 rates) and high COVID-19 hospitalization incidence."

[825] **News Release: *FDA Approves First COVID-19 Vaccine***
Food and Drug Administration (FDA)
August 23, 2021
https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

"Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to **myocarditis** and **pericarditis** following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes."

[826] ***Intravenous injection of COVID-19 mRNA vaccine can induce acute myopericarditis in mouse model***
Clinical Infectious Diseases (Oxford)
Can Li, Yanxia Chen, *et al*.
August 19, 2021
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab707/6353927

"**Methods**: We compared the clinical manifestations, histopathological changes, tissue mRNA expression and serum levels of cytokine/chemokine in Balb/c mice at different time points after intravenous(IV) or intramuscular(IM) vaccine injection with normal saline(NS) control.

Results: Though significant weight loss and higher serum cytokine/chemokine levels were found in IM group at 1 to 2 days post-injection(dpi), only IV group developed histopathological changes of myopericarditis as evidenced by cardiomyocyte degeneration, apoptosis and necrosis with adjacent inflammatory cell infiltration and calcific deposits on visceral pericardium, while evidence of coronary artery or other cardiac pathologies was absent. SARS-CoV-2 spike antigen expression by immunostaining was occasionally found in infiltrating immune cells of the heart or injection site, in cardiomyocytes and intracardiac vascular endothelial cells, but not skeletal myocytes. The histological changes of myopericarditis after the first IV-priming dose persisted for 2 weeks and were markedly aggravated by a second IM- or IV-booster dose. Cardiac tissue mRNA expression of IL-1β, IFN-β, IL-6 and TNF-α increased significantly from 1dpi to 2dpi in IV but not IM group, compatible with presence of myopericarditis in IV group. Ballooning degeneration of hepatocytes was consistently found in IV group. All other organs appeared normal.

Conclusions: This study provided in-vivo evidence that inadvertent intravenous injection of COVID-19 mRNA-vaccines may induce myopericarditis."

[827] **Correspondence: *Myocarditis after Covid-19 mRNA Vaccination***
New England Journal of Medicine
Amanda K. Verma, Kory J. Lavine, and Chieh-Yu Liu
August 18, 2021
https://www.nejm.org/doi/full/10.1056/NEJMc2109975

"The Centers for Disease Control and Prevention recently reported cases of myocarditis and pericarditis in the United States after coronavirus disease 2019 (Covid-19) messenger RNA (mRNA) vaccination.1 In recently published reports, diagnosis of myocarditis was made with the use of noninvasive imaging and routine laboratory testing.2-5 Here, we report two cases of histologically confirmed myocarditis after Covid-19 mRNA vaccination…

In these two adult cases of histologically confirmed, fulminant myocarditis that had developed within 2 weeks after Covid-19 vaccination, a direct causal relationship cannot be definitively established because we did not perform testing for viral genomes or autoantibodies in the tissue specimens. However, no other causes were identified by PCR assay or serologic examination."

[828] ***Association of Myocarditis With BNT162b2 Messenger RNA COVID-19 Vaccine in a Case Series of Children***
JAMA Cardiology
Audrey Dionne, Frencesca Sperotto, *et al*.
August 10, 2021
https://jamanetwork.com/journals/jamacardiology/fullarticle/2783052?utm_campaign=articlePDF

> "**Objective**: To review results of comprehensive cardiac imaging in children with myocarditis after COVID-19 vaccine…
>
> Although vaccine-associated cases of myocarditis to date have had uncomplicated short-term course, the long-term prognosis remains unclear. Of note, CMR [*cardiac magnetic resonance*] LGE [*late gadolinium enhancement*] was a frequent finding at time of diagnosis. In this clinical setting, LGE reflects an increased volume of distribution of the gadolinium-based contrast agent in the affected region likely related to myocyte necrosis and/or extracellular edema. In nonvaccine-associated myocarditis, the presence of LGE is associated with increased risk for adverse cardiovascular events during follow-up.10-12 Thus, longitudinal studies of patients with myocarditis after COVID-19 vaccine will be important to better understand long-term risks."

[829] ***Heart Inflammation Risk Following mRNA COVID-19 Vaccination Could Be Common***
Precision Vaccinations
Don Ward Hackett
August 5, 2021
https://www.precisionvaccinations.com/heart-inflammation-risk-following-mrna-covid-19-vaccination-could-be-common

> "A new study published by the Journal of the American Medical Association (JAMA) on August 4, 2021, found two distinct self-limited heart-related syndromes, myocarditis, and pericarditis, were observed after COVID-19 vaccination.
>
> The US Centers for Disease Control and Prevention (CDC) vaccine committee reported on June 23, 2021, a possible association between mRNA COVID-19 vaccines and myocarditis, primarily in younger male individuals, within a few days after the second vaccination, at an incidence of about 4.8 cases per 1 million.
>
> This new study shows a similar pattern, although at higher incidence, suggesting mRNA COVID-19 vaccine adverse event underreporting."

[830] **ADDED since 2/8/2022**

Heart damage from the COVID vaccines: Is it avoidable?

Primary Doctor Medical Journal
Colleen Huber
July 14, 2021
https://pdmj.org/papers/myocarditis_paper

"**Discussion**: The pathways discussed herein are inevitable routes of spike protein transit in the body and in the cells. ACE2 receptors are abundant in every known cell type. When spike proteins have been introduced to the body, either through the SARS-CoV-2 virus or by means of the mRNA COVID vaccines, is there any realistic way possible to block their interaction with ACE2 receptors in any individual? In the case of acute infection with SARS-CoV-2, infected individuals have a self-limiting encounter with spike proteins, which may be thwarted by some of the therapeutics mentioned above. However, in the case of the mRNA-vaccinated, no endpoint of spike protein production is yet known. Nor is it yet known if it is safe to use any of the spike protein blocking therapeutics in vaccinated individuals.

In the absence of extraordinary and deliberate measures to block ACE2 receptors and CD147 receptors and/or Caspase 3/7 activity, is it then possible to expect that cardiac pericytes and endothelial cells could escape the pro-inflammatory and pro-apoptotic effects of the spike protein, especially considering that protein's perpetual regeneration in vaccinated people? Could a therapeutic be invented for vaccinated people to protect their cardiomyocytes and pericytes from spike protein damage, and to be dosed frequently enough to combat the body's ongoing spike protein production? If such an expectation is not realistic, then mRNA vaccines that prepare human cells to generate an unknown supply of spike proteins for an unknown amount of time are to be treated with extreme caution and avoidance until better understood. It is also necessary to defer further vaccination until there are known methods of both discharge of such proteins and the mechanism to turn off or attenuate mRNA-induced spike proteins, and/or to safely thwart the destructive effects of spike proteins in host cells."

[831] **ADDED since 2/8/2022**

Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings

Journal of Korean Medical Science — Department of Forensic Medicine, South Korea
Sangjoon Choi, SangHan Lee, *et al*.
July 10, 2021
https://jkms.org/DOIx.php?id=10.3346/jkms.2021.36.e286

"**Abstract**: We present autopsy findings of a 22-year-old man who developed chest pain 5 days after the first dose of the BNT162b2 mRNA vaccine and died 7 hours later. Histological examination of the heart revealed isolated atrial myocarditis, with neutrophil and histiocyte predominance. Immunohistochemical C4d staining revealed scattered single-cell necrosis of myocytes which was not accompanied by inflammatory infiltrates. Extensive contraction band necrosis was observed in the atria and ventricles. There was no evidence of microthrombosis or infection in the heart and other organs. The primary cause of death was determined to be myocarditis, **causally-associated with the BNT162b2 vaccine**."

[832] ***Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military***
JAMA Cardiology
Jay Montgomery, Margaret Ryan, Renata Engler, *et al*.
June 29, 2021
https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601

"**Conclusions and Relevance**: In this case series, myocarditis occurred in previously healthy military patients with similar clinical presentations following receipt of an mRNA COVID-19 vaccine. Further surveillance and evaluation of this adverse event following immunization is warranted. Potential for rare vaccine-related adverse events must be considered in the context of the well-established risk of morbidity, including cardiac injury, following COVID-19 infection."

[833] ***COVID-19 Vaccine Safety Technical (VaST) Work Group***
Centers for Disease Control and Prevention (CDC)
Grace M. Lee and Robert H. Hopkins
June 23, 2021
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/04-COVID-Lee-508.pdf

"VaST Discussion and Interpretation:

- Data available to date suggest likely association of myocarditis with mRNA vaccination in adolescents and young adults.
- Clinical presentation of **myocarditis cases following vaccination** has been distinct, occurring most often within one week after dose 2, with chest pain as the most common.
- Further data are being compiled to understand potential risk factors, optimal management strategies, and long-term outcomes."

[834] ***COVID-19 Vaccine safety updates - Advisory Committee on Immunization Practices (ACIP)***
Centers for Disease Control and Prevention (CDC)
Grace M. Lee and Robert H. Hopkins
June 23, 2021
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf

Slide 28: "Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. using 7-day risk window (data thru Jun 11, 2021)"

Compares the expected vs. observed number of myocarditis or pericarditis events occurring within the first 6 days following the second dose of an mRNA inoculation.

- For males 12-17 years of age, the expected number of events was 0-4, but the **observed number** was **128**.
- For males 18-24 years of age, the expected number of events was 1-8, but the **observed number** was **219**.

Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. using 7-day risk window (data thru Jun 11, 2021)

Age groups	Females			Males		
	Doses admin	Expected*,†	Observed*	Doses admin	Expected*,†	Observed*
12–17 yrs	2,189,726	0–2	19	2,039,871	0–4	128
18–24 yrs	5,237,262	1–6	23	4,337,287	1–8	219
25–29 yrs	4,151,975	0–5	7	3,625,574	1–7	59
30–39 yrs	9,356,296	2–18	11	8,311,301	2–16	61
40–49 yrs	9,927,773	2–19	18	8,577,766	2–16	34
50–64 yrs	18,696,450	4–36	18	16,255,927	3–31	18
65+ yrs	21,708,975	4–42	10	18,041,547	3–35	11
Not reported	—	—	1	—	—	8

* Assumes a 7-day post-vaccination observation window (i.e., symptom onset from day of vaccination through Day 6 after vaccination)
† Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:50264-410X(21)00578-8. Expected counts among females 12–29 years adjusted for lower prevalence relative to males by factor of 1.7 (Fairweather, D. et al, *Curr Probl Cardiol.* 2013;38(1):7-46).

[835] **ADDED since 2/8/2022**
Sudden cardiac death risk in contact sports increased by myocarditis: a case series
European Heart Journal Case Reports
Grégoire Massoullié, Baptiste Boyer, *et al.*
March 1, 2021
https://academic.oup.com/ehjcr/article/5/3/ytab054/6154461

"**Background**: Myocarditis is a known cause of sudden cardiac death of the athlete. The impact of direct chest trauma in at-risk sports or activities in patients with a history of myocarditis has never been demonstrated or studied. We report herein two cases of life-threatening ventricular arrhythmia secondary to non-penetrating blunt chest trauma while playing contact sports…

Discussion: Myocarditis **may increase the risk** of life-threatening ventricular arrhythmias caused by blunt impact to the chest, particularly in contact sports. Screening and prevention measures should be considered to reduce this risk."

Cancer

Note: The citations below are presented in reverse, chronological order.

[836] **ADDED since 2/8/2022**
I Have Tried Sounding the Alarm About the Vaccines Causing Cancer Relapse But the Mainstream Media Don't Want to Know
Dr. Angus Dalgleish, Professor of Oncology at St George's Hospital Medical School, London
December 19, 2022
https://dailysceptic.org/2022/12/19/i-have-tried-sounding-the-alarm-about-the-vaccines-causing-cancer-relapse-but-the-mainstream-media-dont-want-to-know/

"Following my recent communication about my very real concern over the recurrence of cancer in many of my melanoma patients who have been stable for long periods, at least five years and in one case 18 years, other oncologists have contacted me to say they are seeing the same phenomenon.

Seeing the recurrence of these cancers after all this time naturally makes me wonder if there is a common cause? I had previously noted that relapse in stable cancer is often associated with severe long-term stress, such as bankruptcy, divorce, etc. However I found that none of my patients had any such extra stress during this time but they had all had booster vaccines and, indeed, a couple of them noted that they had a very bad reaction to the booster which they did not have to the first two injections.

I then noted that some of these patients were not having a normal pattern of relapse but rather an explosive relapse, with metastases occurring at the same time in several sites. Obviously, I began to wonder whether the booster vaccines could be causing these relapses and were not just coincidence."

[837] **ADDED since 2/8/2022**
Letter to the Editor: *As an Oncologist I Am Seeing People With Stable Cancer Rapidly Progress After Being Forced to Have a Booster*
Letter to Dr. Kamran Abbasi, the Editor in Chief of the British Medical Journal
Dr. Angus Dalgleish, Professor of Oncology at St George's Hospital Medical School, London
November 26, 2022
https://dailysceptic.org/2022/11/26/as-an-oncologist-i-am-seeing-people-with-stable-cancer-rapidly-progress-after-being-forced-to-have-a-booster/

"Dear Kamran Abbasi,

Covid no longer needs a vaccine programme given the average age of death of Covid in the U.K. is 82 and from all other causes is 81 and falling.

The link with clots, myocarditis, heart attacks and strokes is now well accepted, as is the link with myelitis and neuropathy. (We predicted these side effects in our June 2020 QRBD article Sorensen et al. 2020, as the blast analysis revealed 79% homologies to human epitopes, especially PF4 and myelin.)

However, there is now another reason to halt all vaccine programmes. As a practising oncologist I am seeing people with stable disease **rapidly progress** after being forced to have a booster, usually so they can travel.

Even within my own personal contacts I am seeing B cell-based disease after the boosters. They describe being distinctly unwell a few days to weeks after the booster – one developing leukaemia, two work colleagues Non-Hodgkin's lymphoma, and an old friend who has felt like he has had Long Covid since receiving his booster and who, after getting severe bone pain, has been diagnosed as having multiple metastases from a rare B cell disorder.

I am experienced enough to know that these are not the coincidental anecdotes that many suggest, especially as the same pattern is being seen in Germany, Australia and the USA.

The reports of innate immune suppression after mRNA for several weeks would fit, as all these patients to date have melanoma or B cell based cancers, which are very susceptible to immune control – and that is before the reports of suppressor gene suppression by mRNA in laboratory experiments.

This must be aired and debated immediately.

Angus Dalgleish MD FRACP FRCP FRCPath FMedSci"

[838] **ADDED since 2/8/2022**

Senior Physician Warns: Aggressive and Unusual Cancers following Covid 'Vaccination' are on the Rise in Sweden (Video)

RAIR Foundation
Miranda Sellick
July 27, 2022
https://rairfoundation.com/senior-physician-warns-aggressive-and-unusual-cancers-following-covid-vaccination-are-on-the-rise-in-sweden-video/

"A senior Swedish physician and researcher is sounding the alarm over the link between Covid-19 vaccinations, fast-growing cancers, and inflammatory conditions of the blood vessels in patients who died following Covid-19 mRNA vaccination.

Dr. Ute Krüger is based at the regional hospital in Kalmar, Sweden. In a recent interview with the Norwegian Association of Doctors and Health Workers (given in Swedish and translated by RAIR Foundation USA), Dr. Krüger expressed alarm at the extraordinary rates of aggressive cancers she is now seeing. Dr. Krüger, who has worked in pathology for 25 years and 18 years in breast cancer diagnostics, has studied 8,000 autopsies and is now convinced of the link between vaccination and death, to say nothing of her conviction that many of her medical colleagues continue to deny these links.

'The vaccines against Covid-19 appear to trigger fast-growing cancers, or porocarcinoma (a type of skin cancer) and also inflammatory conditions in the body, so-called auto-immune diseases,' said Dr. Krüger. 'Maybe this cancer development is linked to the inflammatory conditions. I've talked to other pathologists who are seeing an increased number of tumors that were hardly ever seen before. I mean rare tumors, and that the number of cancer cases has increased in different organs.'"

[839] **ADDED since 2/8/2022**

Video (26m): Interview with Dr. Ute Krüger

Doctors for Covid Ethics
July 22, 2022
https://doctors4covidethics.org/covid-vaccination-and-turbo-cancer-pathological-evidence/
University of Lund:
https://www.lunduniversity.lu.se/lucat/user/e6e028802e163f238d389115c3d8959e

Kruger: "So I have worked in pathology for 25 years. In the last 18 years, I have specializedin breast-cancer diagnostics… In the last seven years, I have also had the opportunity to carry out breast-cancer research at the University of Lund…

[T]here are more and more large and aggressively growing tumors in the tissue samples I examine.

There is one more peculiarity that I have discovered. I believe that lately I'm seeing more patients than before who have had breast cancer in the past and were more or less considered cured. The cancer may have occurred some 20 years ago. Relatively soon after the vaccination against COVID-19, the tumor growth explodes and there is a pronounced spread of the tumor in the body, and the patients die within a few months…

In conclusion, the vaccination against COVID-19 seems to trigger, on the one hand, fast-growing tumors or turbo-cancer and, on the other hand, also inflammatory processes in the body, so-called autoimmune diseases."

[840] **ADDED since 2/8/2022**

Video (5m): Statement by Dr. Richard Urso

Dr. Richard Urso is former Director of Orbital Oncology at MD Anderson Cancer Center
May 15, 2022
https://www.bitchute.com/video/e9uqrREzXfzN/

"What is the distribution of this product, this messenger RNA, this lipid nanoparticle? Well, guess what? It distributes everywhere… The lipid nonparticle does not stay in the arm. In fact, we now know that a large part of it goes into the lymph node, still making spike protein 60 days later…

They never told people that, 'Hey, we're going to stick it in your arm, it's going to show up in your lymph nodes, it's going to show up in your brain, your ovaries, your bone marrow, your adrenal glands, your liver, your spleen, which is then going to track up your Vegas nerve and go to your basal ganglia. All these things are happening. How do I know? Because the studies have been done now…

These studies are done. I'm not giving you opinions, I'm just giving you data. So it goes everywhere, it's **blocking important tumor-repair genes** called P53. It's blocking bracha. It's

also messing with micro-RNA 27A which **causes upticks in colon-cancer cells**… It's messing with toll-like receptors 7 and 8, which (are important for) immune surveillane, for viruses, so we'll see a huge uptick in viruses that lay kind of dormant in our body, like the herpes virus family."

[841] **ADDED since 2/8/2022**

COVID UPDATE: What is the truth?

Surgical Neurology International — Theoretical Neuroscience Research
Russell L Blaylock
April 22, 2022
https://surgicalneurologyint.com/surgicalint-articles/covid-update-what-is-the-truth/

"The Japanese resorted to a FOIA (Freedom of Information Act) lawsuit to force Pfizer to release its secret biodistribution study. The reason Pfizer wanted it kept secret is that it demonstrated that Pfizer lied to the public and the regulatory agencies about the fate of the injected vaccine contents (the mRNA enclosed nano-lipid carrier). They claimed that it remained at the site of the injection (the shoulder), when in fact their own study found that it rapidly spread throughout the entire body by the bloodstream within 48 hours.

The study also found that these deadly nano-lipid carriers collected in very high concentrations in several organs, including the reproductive organs of males and females, the heart, the liver, the bone marrow, and the spleen (a major immune organ). The highest concentration was in the ovaries and the bone marrow. These nano-lipid carriers also were deposited in the brain…

The high concentration of spike proteins found in the ovaries in the biodistribution study could very well impair fertility in young women, alter menstruation, and could put them at an increased risk of ovarian cancer. The high concentration in the bone marrow, could also put the vaccinated at a high risk of **leukemia** and **lymphoma**. The leukemia risk is very worrisome now that they have started vaccinating children as young as 5 years of age. No long-term studies have been conducted by any of these makers of Covid-19 vaccines, especially as regards the risk of cancer induction. Chronic inflammation is intimately linked to cancer induction, growth and invasion and vaccines stimulate inflammation.

Cancer patients are being told they should get vaccinated with these deadly vaccines. This, in my opinion, is insane. Newer studies have shown that this type of vaccine inserts the spike protein within the nucleus of the immune cells (and most likely many cell types) and once there, inhibits two very important DNA repair enzymes, BRCA1 and 53BP1, whose duty it is to repair damage to the cell's DNA.[29] **Unrepaired DNA damage** plays a major role in cancer.

There is a hereditary disease called xeroderma pigmentosum in which the DNA repair enzymes are defective. These ill-fated individuals develop multiple skin cancers and a very high incidence of organ cancer as a result. Here we have a vaccine that does the same thing, but to a less extensive degree.

One of the defective repair enzymes caused by these vaccines is called BRCA1, which is associated with a significantly higher incidence of breast cancer in women and prostate cancer in men."

[842] **ADDED since 2/8/2022**
Video (82m): *How COVID Shots Suppress Your Immune System*
Joseph Mercola interviews Stephanie Seneff, senior research scientist at the MIT Computer Science and Artificial Intelligence Laboratory
February 2022
https://rumble.com/vtcggx-how-covid-shots-supress-your-immune-system-interview-with-stephanie-seneff-.html

See [864].

[843] ***Letter from Senator Ron Johnson to Lloyd J. Austin III, Secretary of the Department of Defense***
February 1, 2022
https://www.ronjohnson.senate.gov/services/files/FB6DDD42-4755-4FDC-BEE9-50E402911E02

"Dear Secretary Austin: On January 24, 2022, I held a roundtable featuring world renowned doctors and medical experts who shared their perspectives on COVID-19 vaccine efficacy and safety and the overall response to the pandemic. At that roundtable, I heard testimony from Thomas Renz, an attorney who is representing three Department of Defense (DoD) whistleblowers, who revealed disturbing information regarding dramatic increases in medical diagnoses among military personnel. The concern is that these increases may be related to the COVID-19 vaccines that our servicemen and women have been mandated to take.

Based on data from the Defense Medical Epidemiology Database (DMED), Renz reported that these whistleblowers found a significant increase in registered diagnoses on DMED for miscarriages, cancer, and many other medical conditions in 2021 compared to a five-year average from 2016-2020… There were also increases in registered diagnoses in 2021 for the following medical conditions [*emphasis added*]: …

- Breast cancer – 487% increase…
- Testicular cancer – 369% increase
- **Video (4m): *Attorney Thomas Renz reveals new vaccine injury whistleblower data during Senator Ron Johnson COVID-19 committee***
  January 24, 2022
  https://odysee.com/@NewsClips:f/Attorney-Thomas-Renz-Senator-Ron-Johnson-Jan.-24:f

Johnson: "So these are whistleblowers who have been extracting data out of the Defense Department database, they have noticed a very alarming increase in instances of certain conditions compared to a 5-year average…"

Renz: "… we have three whistleblowers at this point who have given me permission to share their name… All three have given me this data. I have declarations from all three and this is under penalty of perjury…

Miscarriages increased by 300% over the 5-year average. We saw almost a **300% increase in cancer** over the 5-year average [*emphasis added*]…

Johnson: "So again, the Department of Defense and the Biden administration is on notice - they must preserve these records and this must be investigated."

[844] **ADDED since 2/8/2022**

Thousands report developing abnormal tumors following COVID shots

Lifesite News
Celeste McGovern
November 1, 2021
https://www.lifesitenews.com/news/thousands-report-developing-abnormal-tumors-following-covid-shots/

"A few doctors have spoken out about the spikes in cancer they have seen. 'Since January 1, in the laboratory, I'm seeing a 20-times increase of endometrial cancers over what I see on an annual basis,' pathologist and immunologist/virologist Ryan Cole told Health Freedom Idaho. 'I'm not exaggerating at all because I look at my numbers year over year, and I'm like 'Gosh, I've never seen this many endometrial cancers before.'' Cole said he's seeing invasive melanomas in young people 'skyrocketing.'

'I've seen three people who developed pancreatic cancers within weeks of vaccines,' a doctor in an American college town who wishes to remain anonymous told LifeSiteNews. He has also seen a case of prostate cancer that rapidly became aggressive and a breast cancer that suddenly became so big it filled a quarter of a woman's chest wall. 'They're so aggressive, they're untreatable,' he said. 'I might recall one case like this, these are once in a blue moon events,' but he added that he has heard other doctors speak of seeing similar cases recently, as well.

Possible mechanism

Mechanisms underpinning vaccine-induced malignancies are unknown, but not implausible.

'We are modifying the immune system to a weakened state,' Cole said in his interview with Health Freedom Idaho, citing unpublished research that showed that Pfizer's vaccine had the unintended effect of modulating the immune system to promote inflammatory molecules.

'The mechanisms of reported data on covid-19 vaccines associated with diagnosis of rapid tumor or cancer growth are likely similar to the observations we reported in 1980's,' former program director at the National Institutes of Health, National Cancer Institute, molecular biologist and immunologist Mahin Khatami, referring to studies where an antigen (a foreign element that is capable of stimulating the immune system to potentially cause synthesis of specific antibodies) was mixed with tumor promoting agents (TPAs) shifted the growth of tumors to earlier time-frames (within 6 months, instead of 12 to 30 months).

'These studies suggested enhanced activation of kinases [enzymes] and related growth promoting mediators in rapid induction of tumor growth,' Khatami, author of Inflammation, Aging and Cancer told LifeSite News.

Khatami added that in her opinion, 'COVID vaccines could further promote chronic (unresolved) inflammation' that could set of a cascade of biological activities promoting tissue growth. 'Covid vaccines could induce exacerbation of expression of growth-promoting cytokines that shift the time-frame of slow tissue growth to rapidly induce benign tumors or cancer metastasis.'"

[845] **Video (2m): Interview with Dr. Ryan Cole, pathologist**
August 25, 2021
https://twitter.com/ToTheLifeboats/status/1430589141344034816

Cole: "What we're seeing in the laboratory after people get these shots, we're seeing a very concerning, locked-in, low profile of these important killer T cells that you want in your body… **What we're seeing is a drop in your killer T cells**, your CD8 cells. And what do CD8 cells do? They keep all other viruses in check [*emphasis added*].

What am I seeing in the laboratory? I'm seeing an uptick of herpes family viruses, … I'm seeing shingles, I'm seeing mono, I'm seeing a huge uptick in human papilloma virus in the cervical biopsies and the cervical pap smears in women…

We're literally weakening the immune systems of these individuals. Now, most concerning of all, is there's a pattern of the types of immune cells in the body that keep cancer in check. Well, since January 1 in the laboratory, I've seen a **20x of endometrial cancers** over what I see on an annual basis [*emphasis added*]. A 20x increase. Not exaggerating at all because I look at my numbers, year over year…

I'm seeing invasive melanomas in younger patients. Normally we catch those early and they're thin melanomas. I'm seeing thick melanomas skyrocketing in the past month or two.

I'm already seeing the early signals and we are modifying the immune system to a weakened state. Great study out of Germany that looked at these profiles on young individuals, after the Pfizer [shot]…"

Neurological Disorders

Note: The citations below are presented in reverse, chronological order.

[846] **ADDED since 2/8/2022**
Dr Kerryn Phelps reveals 'devastating' Covid vaccine injury, says doctors have been 'censored'
news.com.au
Frank Chung
December 20, 2022
https://www.news.com.au/technology/science/human-body/dr-kerryn-phelps-reveals-devastating-covid-vaccine-injury-says-doctors-have-been-censored/news-story/0c1fa02818c99a5ff65f5bf852a382cf

> "Former federal MP Dr Kerryn Phelps has revealed she and her wife both suffered serious and ongoing injures from Covid vaccines, while suggesting the true rate of adverse events is far higher than acknowledged due to underreporting and 'threats' from medical regulators.
>
> In an explosive submission to Parliament's Long Covid inquiry, the former Australian Medical Association (AMA) president has broken her silence about the 'devastating' experience — emerging as the most prominent public health figure in the country to speak up about the taboo subject…
>
> 'I continue to observe the devastating effects a year-and-a-half later with the addition of fatigue and additional neurological symptoms including nerve pains, altered sense of smell, visual disturbance and musculoskeletal inflammation. The diagnosis and causation has been confirmed by several specialists who have told me that **they have seen 'a lot' of patients in a similar situation**…'
>
> Dr Phelps revealed she was also diagnosed with a vaccine injury from her second dose of Pfizer in July 2021, 'with the diagnosis and causation confirmed by specialist colleagues.' …
>
> She revealed she had spoken with other doctors 'who have themselves experienced a serious and persistent adverse event' but that 'vaccine injury is a subject that few in the medical profession have wanted to talk about.'
>
> 'Regulators of the medical profession have **censored public discussion about adverse events** following immunisation, with **threats to doctors** not to make any public statements about anything that 'might undermine the government's vaccine rollout' or **risk suspension or loss of their registration**,' she said."

[847] **ADDED since 2/8/2022**
COVID-19 Vaccine-Associated Optic Neuropathy: A Systematic Review of 45 Patients
Vaccines — National Institutes of Health
Ayman G. Elnahry, Mutaz Y. Al-Nawaflh, *et al*.
October 20, 2022
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9609672/pdf/vaccines-10-01758.pdf

> "**Abstract**: We provide a systematic review of published cases of optic neuropathy following COVID-19 vaccination. We used Ovid MEDLINE, PubMed, and Google Scholar. Search terms

included: 'COVID-19 vaccination',' optic neuropathy', 'optic neuritis', and 'ischemic optic neuropathy'. The titles and abstracts were screened, then the full texts were reviewed…

"**Discussion**: In this systematic review of published cases of optic neuropathy following COVID-19 vaccination, we found that **COVID-19 vaccination was associated with several forms of optic neuropathy**, most commonly AION [*anterior ischemic optic neuropathy*] and optic neuritis. All subtypes of COVID-19 vaccines, including mRNA, viral vector, and inactivated viral vaccines were associated with optic neuropathy. However, protein subunit vaccines, such as the Novavax vaccine, were not reported as a cause of optic neuropathy in the current review. **The temporal association between vaccine administration and the development of optic neuropathies in these cases makes a causal link plausible**, with a mean time from vaccination to the development of ocular symptoms of 9.6 ± 8.7 days. Cases with a late onset of optic neuropathy, however, are less likely to be related to vaccination and could be coincidental. Vaccines and their adjuvants are meant to robustly activate the innate immune system, and adaptive immunity then follows. Overactivation of this response, however, may occur in some patients and lead to rare immune-mediated complications…

Conclusions: In conclusion, several cases of optic neuropathy were reported following the administration of COVID-19 vaccines, suggesting an association and perhaps a cause–effect relationship, with at least one case reporting a positive rechallenge phenomenon following the second dose of vaccination."

[848] **ADDED since 2/8/2022**

Towards the emergence of a new form of the neurodegenerative Creutzfeldt-Jakob disease: Twenty six cases of CJD declared a few days after a COVID-19 "vaccine" Jab

Jean Claude Perez, Claire Moret-Chalmin, and Luc Montagnier

June 2022

https://canadahealthalliance.org/wp-content/uploads/2022/06/V2CJDPerezMoretMontagnierRIP2022REFERENCEARTICLE.pdf

"**Abstract**: … We are studying 26 Creutzfeld Jakob Diseases, in 2021, from an anamnestic point of view, centered on the chronological aspect of the evolution of this new prion disease, without being able to have an explanation of the etiopathogenic aspect of this new entity. We subsequently recall the usual history of this dreadfull subacute disease, and compare it with this new, extremely acute, prion disease, following closely vaccinations. In a few weeks, more 50 cases of almost spontaneous emergence of Creutzfeldt-Jakob disease have appeared in France and Europe very soon after the injection of the first or second dose of Pfizer, Moderna or AstraZeneka vaccines. To summarize, of the 26 cases analyzed, the first symptoms of CJD appeared on average 11.38 days after the injection of the COVID-19 'vaccine'. Of these 26 cases, 20 had died at the time of writing this article while 6 were still alive. The 20 deaths occurred only 4.76 months after the injection. Among them, 8 of them lead to a sudden death (2.5 months). All this confirms the radically different nature of this new form of CJD, whereas the classic form requires several decades."

[849] **ADDED since 2/8/2022**

Neuropathic symptoms with SARS-CoV-2 vaccination

National Institutes of Health

Farnaz Safavi, Lindsey Gustafson, *et al*.

May 17, 2022

https://www.medrxiv.org/content/10.1101/2022.05.16.22274439v1

"**Background and Objectives**: Various peripheral neuropathies, particularly those with sensory and autonomic dysfunction may occur during or shortly after acute COVID-19 illnesses. These appear most likely to reflect immune dysregulation. If similar manifestations can occur with the vaccination remains unknown.

Results: In an observational study, we studied 23 patients (92% female; median age 40 years) reporting new neuropathic symptoms beginning within 1 month after SARS-CoV-2 vaccination. **100%** reported sensory symptoms comprising severe face and/or limb paresthesias, and **61%** had orthostasis, heat intolerance and palpitations … Together, 52% (12/23) of patients had objective evidence of small-fiber peripheral neuropathy…

Conclusions: This observational study suggests that **a variety of neuropathic symptoms may manifest after SARS-CoV-2 vaccinations** and in some patients might be an immune-mediated process."

[850] **ADDED since 2/8/2022**

SARS-CoV-2 Proteins Interact with Alpha Synuclein and Induce Lewy Body-like Pathology In Vitro

International Journal of Molecular Sciences — Chinese Academy of Medical Sciences and Peking Union Medical College

Zhengcun Wu, Xiuao Zhang, Zhangqiong Huang, and Kaili Ma

March 21, 2022

https://www.mdpi.com/1422-0067/23/6/3394

"**Abstract**: Growing cases of patients reported have shown a potential relationship between (severe acute respiratory syndrome coronavirus 2) SARS-CoV-2 infection and **Parkinson's disease** (PD). However, it is unclear whether there is a molecular link between these two diseases. Alpha-synuclein (α-Syn), an aggregation-prone protein, is considered a crucial factor in PD pathology. In this study, bioinformatics analysis confirmed favorable binding affinity between α-Syn and SARS-CoV-2 spike (S) protein and nucleocapsid (N) protein, and direct interactions were further verified in HEK293 cells. The expression of α-Syn was upregulated and its aggregation was accelerated by S protein and N protein. It was noticed that SARS-CoV-2 proteins caused **Lewy-like pathology** in the presence of α-Syn overexpression. By confirming that SARS-CoV-2 proteins directly interact with α-Syn, our study offered new insights into the mechanism underlying the development of PD on the background of COVID-19."

[851] **ADDED since 2/8/2022**

COVID-19 Vaccination and Neurological Manifestations: A Review of Case Reports and Case Series

Brain Sciences — West Virginia University
Shitiz Sriwastava, Kanika Sharma, *et al*.
March 18, 2022
https://www.mdpi.com/2076-3425/12/3/407

"**Background**: With 10 vaccines approved by the WHO and nearly 48% of people fully vaccinated worldwide, we have observed several individual case studies of neurological manifestations post-COVID-19 vaccination. Through this systematic review, we aim to discern these CNS and PNS manifestations following the COVID-19 vaccine to help produce methods to mitigate them.

Methods: We conducted a thorough literature search of Google Scholar and PubMed from 1 December 2020 until 10 October 2021 and included all the case studies of COVID-19 vaccine-associated neurological side effects. The literature search and data analysis were performed by two independent reviewers according to prespecified inclusion and exclusion criteria using PRISMA.

Results: The most common CNS [*central nervous system*] manifestation was **CVST** (14.47%), found in females (64%) younger than 50 years (71%) after the first AstraZeneca dose (93%). Others included **CNS demyelinating disorders** (TM, ADEM, MS, NMOSD) (9.30%), **encephalopathy/encephalitis** (3.10%), and others (4.13%). The most common PNS manifestation was **GBS** (14.67%) found in males (71%) older than 50 years (79%), followed by **Bell's palsy** (5.24%) and others (2.10%). Most occurred with the AstraZeneca (28.55%), Pfizer-BioNTech (9.18%), and Moderna (8.16%) vaccines. Nine (64%) out of the 14 patients with CVST died."

Key:

CVST - cerebral venous sinus thrombosis

TM – transverse myelitis

ADEM – acute disseminated encephalomyelitis

MS – multiple sclerosis

NMOSD - neuromyelitis optica spectrum disorder

PNS - peripheral nervous system

GBS - Guillain–Barré syndrome

[852] ***COVID-19 Vaccine Associated Parkinson's Disease, A Prion Disease Signal in the UK Yellow Card Adverse Event Database***
Journal of Medical-Clinical Research & Reviews
J. Bart Classen
July 18, 2021
https://scivisionpub.com/pdfs/covid19-vaccine-associated-parkinsons-disease-a-prion-disease-signal-in-the-uk-yellow-card-adverse-event-database-1746.pdf

"**Abstract**: Many have argued that SARS-CoV-2 spike protein and its mRNA sequence, found in all COVID-19 vaccines, are priongenic. The UK's Yellow Card database of COVID-19 vaccine adverse event reports was evaluated for signals consistent with a pending epidemic of COVID vaccine induced prion disease. Adverse event reaction rates from AstraZeneca's vaccine were compared to adverse event rates for Pfizer's COVID vaccines. The vaccines employ different technologies allowing for potential differences in adverse event rates but allowing each to serve as a control group for the other. The analysis showed a highly statistically significant and clinically relevant (2.6-fold) increase in Parkinson's disease, a prion disease, in the AstraZeneca adverse reaction reports compared to the Pfizer vaccine adverse reaction reports (p= 0.000024)..."

[853] **ADDED since 2/8/2022**
Guillain-Barré Syndrome Variant Occurring after SARS-CoV-2 Vaccination
Annals of Neurology — Nottingham University, UK
Christopher Martin Allen, Shelby Ramsamy, *et al*.
June 10, 2021
https://onlinelibrary.wiley.com/doi/10.1002/ana.26144

"**Abstract**: Although SARS-CoV-2 vaccines are very safe, we report 4 cases of the bifacial weakness with paresthesias variant of Guillain–Barré syndrome (GBS) occurring within 3 weeks of vaccination with the Oxford–AstraZeneca SARS-CoV-2 vaccine. This rare neurological syndrome has previously been reported in association with SARS-CoV-2 infection itself. Our cases were given either intravenous immunoglobulin, oral steroids, or no treatment. We suggest vigilance for cases of bifacial weakness with paresthesias variant GBS following vaccination for SARS-CoV-2 and that postvaccination surveillance programs ensure robust data capture of this outcome, to assess for causality."

Autoimmunity and Autoimmune Disorders

Definitions:

"**autoimmunity**: a condition characterized by a specific humoral or cell-mediated immune response against the constituents of the body's own tissues (autoantigens); it may result in hypersensitivity reactions or, if severe, in autoimmune disease."
https://medical-dictionary.thefreedictionary.com/autoimmunity

"**autoimmune disease**: disease associated with the production of antibodies directed against one's own tissues."
https://medical-dictionary.thefreedictionary.com/Autoimmune+disease

"**[m]embranous nephropathy (MN)** is a disorder where the body's immune system attacks the filtering membranes in the kidney. These membranes clean waste products from the blood."
https://my.clevelandclinic.org/health/diseases/21154-membranous-nephropathy

Note: The citations below are presented in reverse, chronological order.

[854] **ADDED since 2/8/2022**
Why Do Vaccinated People Represent Most COVID-19 Deaths Right Now?
Epoch Times
George Citroner
January 6, 2023
https://www.theepochtimes.com/health/why-do-vaccinated-people-represent-most-covid-19-deaths-right-now_4964658.html

"Dr. Robert G. Lahita, director of the Institute for Autoimmune and Rheumatic Disease at Saint Joseph Health, said the new booster is a tough sell because people are sick of vaccinations.

'People were told that the vaccine would prevent infection and it did not,' he continued. 'The man in the street sees only his family and friends sick over and over again and they have all been vaccinated, so he says 'what's the point?'…

Lahita noted that turning our population—and especially our children—into "pincushions for more and more vaccines" isn't the best idea.

'What I have found in my 50 years in medicine is that, **as people take more and more boosters of the same vaccine, I see greater toxicity**,' he noted…

The recent COVID-19 outbreak in China also raises concerns…

According to the most recent data, nearly 90 percent of the Chinese mainland population has been fully vaccinated.

'The Chinese outbreaks are worrisome,' explained Lahita, 'because the virus tends to upregulate and mutate in large infected groups.' This could bring about a new spike in COVID-19 infections worldwide, as new variants appear—against which we'll have no naturally acquired or vaccine-induced protection.

'I expect a new and possibly lethal variant for the near future,' Lahita warned."

[855] **ADDED since 2/8/2022**
New-Onset and Relapsed Membranous Nephropathy post SARS-CoV-2 and COVID-19 Vaccination
Viruses — The Second Affiliated Hospital of Nanchang University, China
Qiqi Ma, Xiang Li, and Gaosi Xu
September 28, 2022
https://www.mdpi.com/1999-4915/14/10/2143

"**Abstract**: Since the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outbreak and COVID-19 vaccination, new-onset and relapsed clinical cases of membranous nephropathy (MN) have been reported. However, their clinical characteristics and pathogenesis remained unclear. In this article, we collected five cases of MN associated with SARS-CoV-2 infection and **37 related to COVID-19 vaccination**. Of these five cases, four (4/5, 80%) had acute kidney injury (AKI) at disease onset. Phospholipase A2 receptor (PLA2R) in kidney tissue was negative in three (3/5, 60%) patients, and no deposition of virus particles was measured among all patients. Conventional immunosuppressive drugs could induce disease remission. The underlying pathogenesis included the subepithelial deposition of viral antigens and aberrant immune response. New-onset and relapsed MN after COVID-19 vaccination generally occurred within two weeks after the second dose of vaccine. Almost **27% of patients** (10/37) **suffered from AKI**."

[856] **ADDED since 2/8/2022**
Incidence of Guillain-Barré Syndrome After COVID-19 Vaccination in the Vaccine Safety Datalink
JAMA Network Open
Kayla E. Hanson, Kristin Goddard, *et al*.
April 26, 2022
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2791533

"**Question**: Are COVID-19 vaccines associated with Guillain-Barré syndrome (GBS)?

Findings: In this cohort study of surveillance data from the Vaccine Safety Datalink that included 15.1 million doses of COVID-19 vaccines, the unadjusted incidence rate of confirmed GBS in the 1 to 21 days after receiving the Ad.26.COV2.S (Janssen) vaccine was 32.4 per 100 000 person-years, which was significantly higher than the background rate of GBS. The unadjusted incidence rate of confirmed GBS in the 1 to 21 days after mRNA vaccines was 1.3 per 100 000 person-years, which did not differ from the background rate.

Meaning: These findings suggest an increased risk of GBS after Ad.26.COV2.S vaccination."

[857] ***Thyrotoxicosis following SARS-COV-2 vaccination: a case series and discussion***
Journal of Endocrinological Investigation (Hospital General Universitario de Castellón, Spain)
B. Pla Peris, A.A. Merchante Alfaro, *et al*.
January 11, 2022
https://link.springer.com/article/10.1007/s40618-022-01739-0#author-information

"**Results**: We report 8 cases with thyrotoxicosis after SARS-CoV-2 vaccination. 4 cases of Graves' disease (GD), 2 cases of subacute painful thyroiditis (SAT), 1 case of concurrent GD

and SAT and 1 case of atypical subacute thyroiditis. Five patients received BNT162b2 mRNA vaccine, 3 patients 1273 mRNA vaccine. The onset of symptoms following vaccination ranged from 10 to 14 days in six of eight patients and from 7 to 8 weeks in two patients.

Conclusions: Several hypotheses have been proposed to explain the potential correlation between SARS-CoV-2 vaccination and thyrotoxicosis, including immune system hyper-stimulation, molecular mimicry and Autoimmune/Autoinflammatory Syndrome Induced by Adjuvants (ASIA). We should pay greater attention to thyroid disorders in patients receiving vaccine against SARS-CoV-2."

[858] ***New-onset autoimmune phenomena post-COVID-19 vaccination***
Immunology (Anhui Medical University, China)
Yue Chen, Zhiwei Xu, et al.
December 27, 2021
https://onlinelibrary.wiley.com/doi/10.1111/imm.13443

"**Abstract**: … Vaccination programmes are being rolled out globally, but most of these vaccines have been approved without extensive studies on their side-effects and efficacy. Recently, new-onset autoimmune phenomena after COVID-19 vaccination have been reported increasingly (e.g. immune thrombotic thrombocytopenia, autoimmune liver diseases, Guillain–Barré syndrome, IgA nephropathy, rheumatoid arthritis and systemic lupus erythematosus). Molecular mimicry, the production of particular autoantibodies and the role of certain vaccine adjuvants seem to be substantial contributors to autoimmune phenomena. However, whether the association between COVID-19 vaccine and autoimmune manifestations is coincidental or causal remains to be elucidated. Here, we summarize the emerging evidence about autoimmune manifestations occurring in response to certain COVID-19 vaccines. Although information pertaining to the risk of autoimmune disease as a consequence of vaccination is controversial, we merely propose our current understanding of autoimmune manifestations associated with COVID-19 vaccine…

Conclusion: In the light of the information discussed above, **emerging evidence has indicated that new onset of autoimmune manifestations** including VITT [*vaccine-induced immune thrombotic thrombocytopenia*], autoimmune liver diseases, GBS and IgA nephropathy **appears to be associated with COVID-19 vaccines** (Table 2). The plausible mechanisms by which COVID-19 vaccines lead to autoimmune manifestations include molecular mimicry, the production of particular autoantibodies and the role of certain vaccine adjuvants [*emphasis added*]."

[859] ***Reaction of Human Monoclonal Antibodies to SARS-CoV-2 Proteins With Tissue Antigens: Implications for Autoimmune Diseases***
Frontiers in Immunology
Aristo Vojdani, Elroy Vojdani, and Datis Kharrazian
January 19, 2021
https://www.frontiersin.org/articles/10.3389/fimmu.2020.617089/full

"**Discussion**: … Our study also identified several cross-reactive interactions that may lead to specific autoimmune patterns. For example, we found that SARS-CoV-2 spike protein, nucleoprotein, and membrane protein all cross-reacted with TPO [thyroid peroxidase]…

In a very recent publication in JAMA, Trogen et al. said, 'What cannot and must not be allowed is for desperation to result in the suspension of scientific principles and ethical research values.' We ourselves would apply these principles and ethical values towards investigating whether SARS-CoV-2 peptides contained in a future vaccine may cross-react with human tissue antigens and possibly result in autoimmunity. But while the possibility of future autoimmune disease is daunting and very real, it must be remembered that without vaccinations the SARS-CoV-2 pandemic will spread unchecked, bringing with it a slew of multiple system disorders including autoimmunities both in the present and the future."

[860] ***Pathogenic priming likely contributes to serious and critical illness and mortality in COVID-19 via autoimmunity***
Journal of Translational Autoimmunity
James Lyons-Weiler
April 9, 2020
https://www.sciencedirect.com/science/article/pii/S2589090203001867?via%3Dihub

"**Highlights**: The list of viral/human protein matches… indicates which epitopes might be responsible for autoimmunological pathogenic priming due to prior infection or following exposure to SARS-CoV-2 or relatives following vaccination. These epitopes should be excluded from vaccines under development to minimize autoimmunity due to risk of pathogenic priming…

Discussion: … The fact that pathogenic priming may be occurring involving autoimmunity against multiple proteins following CoV vaccination is consistent with other observations observed during autoimmunity, including the release of proinflammatory cytokines and cytokine storm. Similar to the SARS-CoV animal studies [6], found that mice vaccinated against MERS-CoV (Middle East Respiratory Syndrome) development exaggerated pulmonary immunopathology when challenged with the MERS virus following vaccination."

Immunodeficiency and Immunopathological Disorders

Definitions:

"**Immunodeficiency disorders** are immune system malfunctions that may prevent a person's body from defending itself against disease or infection. It could mean the body's immune system doesn't produce enough immune cells or antibodies to fight off foreign invaders or that the body's immune response is absent."
https://www.livescience.com/immunodeficiency

Note: The citations below are presented in reverse, chronological order.

[861] **ADDED since 2/8/2022**
Hybrid and herd immunity 6 months after SARS-CoV-2 exposure among individuals from a community treatment program
Nature Scientific Reports — Mahidol University, Thailand
Parawee Chevaisrakul, Putthapoom Lumjiaktase, *et al*.
January 14, 2023
https://www.nature.com/articles/s41598-023-28101-5

"**Abstract**: … Hybrid immunity provided by a combination of vaccination and infection, including asymptomatic infection, may confer effective protection against death. We explored the combined effect of asymptomatic infection and hybrid immunity by studying T-cell and antibody responses against SARS-CoV-2 among individuals treated in home health care services 6 months after SARS-CoV-2 exposure. Asymptomatic SARS-CoV-2 infection was demonstrated in 24.4% of close contacts. The levels of immunity were not different between patients and close contacts. Anti-RBD IgG against SARS-CoV-2 increased in a dose-dependent manner with the number of vaccine doses. Interestingly, the T-cell response **decreased** soon after a booster dose of vaccine. Asymptomatic SARS-CoV-2 infection could not enhance immunity against SARS-CoV-2 among vaccinated close contacts. Full vaccination was crucial to provide hybrid immunity. However, when designing vaccine strategies, T-cell exhaustion after multiple vaccinations should be considered…

Results: … After vaccination, increments of RBD IgG levels were observed in a dose-dependent manner according to the number of vaccine doses among both patients and close contacts. However, the T-cell response did not increase in the same pattern as RBD IgG. There was a **significant decrease in T-cell responses** against the S antigen in participants who received three and four doses of the vaccine."

[862] **ADDED since 2/8/2022**

Extended SARS-CoV-2 RBD booster vaccination induces humoral and cellular immune tolerance in mice

iScience — Chongqing Medical University, China

Feng-Xia Gao, Rui-Xin Wu, *et al*.

November 2, 2022

https://www.cell.com/iscience/fulltext/S2589-0042(22)01751-5

"**Summary**: The repetitive applications of vaccine boosters have been brought up in face of continuous emergence of SARS-CoV-2 variants with neutralization escape mutations, but their protective efficacy and potential adverse effects remain largely unknown. Here, we compared the humoral and cellular immune responses of an extended course of recombinant receptor binding domain (RBD) vaccine boosters with those from conventional immunization strategy in a Balb/c mice model. Multiple vaccine boosters after the conventional vaccination course significantly decreased RBD-specific antibody titers and serum neutralizing efficacy against the Delta and Omicron variants, and profoundly impaired CD4+ and CD8+T cell activation and increased PD-1 and LAG-3 expressions in these T cells. Mechanistically, we confirmed that extended vaccination with RBD boosters overturned the protective immune memories by promoting adaptive immune tolerance. Our findings demonstrate **potential risks with the continuous use of SARS-CoV-2 vaccine boosters**, providing immediate implications for the global COVID-19 vaccination enhancement strategies…

Discussion: Currently, vaccination against COVID-19 has been promoted worldwide, although sustained protection against the newly emerged SARS-CoV-2 variant strains has been continuously challenged. Clinical evidence has proven that the inclusion of an additional booster vaccine can re-stimulate the protective immune response (Cheng et al., 2022; Gruell et al., 2022). Whether such re-establishment of vaccine-induced immune response could be repeated by continued application of boosters is being questioned, yet largely unknown at present. Here, we compared the effects of repeated RBD vaccine boosters with a conventional immunization course to those with an extended vaccination strategy, in a Balb/c mice model. We found that the protective effects from the humoral immunity and cellular immunity established by the conventional immunization were both **profoundly impaired** during the extended vaccination course. Specifically, extended vaccination not only **fully impaired** the amount and the neutralizing efficacy of serum RBD-specific antibodies, but also shortened the long-term humoral memory. This is associated with immune tolerance in germinal center response, along with decreased numbers of spleen germinal center B and Tfh cells. Moreover, we demonstrated that extended immunization **reduced** the functional responses of CD4+ and CD8+T cells, **restrained** the population of memory T cells, and up-regulated the expression of PD-1 and LAG-3 in Te sub-type cells. An increased percentile of Treg cells was also observed, accompanied by significant elevation of IL-10 production. Together, we provided crucial evidence that repetitive administration of RBD booster vaccines may negatively impact the immune response established by a conventional vaccination course and promote adaptive immune tolerance."

[863] **ADDED since 2/8/2022**

What you need to know about 'original antigenic sin' with fall COVID boosters around the corner

ABC News
Youri Benadjaoud and Emma Egan
September 7, 2022
https://abcnews.go.com/Health/original-antigenic-sin-fall-covid-boosters-corner/story?id=89229663

> "Some experts say they are concerned that frequent boosting with the original version of the vaccine may have inadvertently exacerbated immune imprinting. At this point in the pandemic, some adults have received four or more doses of the same vaccine…
>
> Although still theoretical, some scientists worry about a potential backfire, with frequent boosting **handcuffing the body's natural immune system** and leaving it exposed to radically different variants that might emerge in the future.
>
> 'Where this matters is if you keep giving booster doses with [original] strain, and continue to lock people into that original response. It makes it harder for them to respond then to essentially a completely different virus,' says Dr. Paul Offit, professor of pediatrics at Children's Hospital Philadelphia…
>
> The timing of vaccines may also need to be taken into account, as the nation moves from original doses to updated boosters.
>
> 'It is true that the best boosts typically are the ones that are given infrequently, that immunologically, if you boost too much and too frequently, then you often have a lower immune response at the end,' said [director of the center for virology and vaccine research at Beth Israel Deaconess Medical Center, Dr. Dan] Barouch."

[864] **ADDED since 2/8/2022**

Video (82m): *How COVID Shots Suppress Your Immune System*

Joseph Mercola interviews Stephanie Seneff, senior research scientist at the MIT Computer Science and Artificial Intelligence Laboratory
February 2022
https://rumble.com/vtcggx-how-covid-shots-supress-your-immune-system-interview-with-stephanie-seneff-.html

> **Seneff**: "It's just amazing, because [*reports of cancer are*] overall two times [*higher*]. Breast cancer, for example, is three times [*higher*] for these vaccines in one year, as they are for all the other vaccines for 31 years. It's a hugely strong signal.
>
> Lymphoma is also showing up much more frequently with these [*COVID shots*]. There's just an amazing signal there in VAERS [*the U.S. Vaccine Adverse Events Reporting System*]…
>
> It's ironic that the vaccines are being given to protect you from COVID, yet, they produce a situation where your immune cells are ill-equipped to fight SARS-CoV-2 if it gets into the cell…
>
> The immune cells take up the nanoparticles and carry them through the lymph system into the spleen. Multiple studies have shown that it ends up in the spleen … the ovaries, the liver, the bone marrow … The spleen, of course, is very important for producing antibodies…

It's as if the human immune cells suddenly decided to make a really toxic protein, and make lots of it — which is exactly what they're doing — and the immune system is completely baffled by this. The immune cells have no clue what to do with it.

Of course, these immune cells that are overloaded with all this spike protein, they say, 'I've got to get rid of this stuff,' so they ship it out as these exosomes. The microRNAs *[in the exosomes*] think that the recipient cells are going to need those particular signaling molecules to help it do whatever it needs to do to cope with this toxic load.

After something like 14 days of the second [*jab*], the exosomes induced an antibody response. [*The researchers*] felt the exosomes played a critical role in this extreme antibody response that was produced by the B-cells and the T-cells, the adaptive immune system…

There's a crossover point at which the enhancing antibodies can be stronger than the protective antibodies, and that's when you can get this antibody dependent enhancement (ADE) that people have seen in the past with [*other*] coronavirus vaccines. We're still trying to see if that's the case with [*the COVID jabs*]. There is some evidence here and there, but it's not [*conclusive yet*]…

Kanduc has written a lot about this. She's an expert on these antibodies … The [*SARS-CoV-2*] spike protein is very overlapped with human protein. That means when you build a really strong antibody response to the spike protein, those antibodies can get confused and they can **attack a human protein** that has a similar sequence.

That's a classic form of autoimmune disease. It's called molecular mimicry. There were many different proteins that matched. It was quite surprising … It seems to be very well designed to induce autoimmune disease, if you produce antibodies to those sequences in the spike protein…

I think we're going to see people getting these neurodegenerative diseases earlier and earlier in life than they used to, and I think **anybody who already has any of these diseases is going to have accelerated progression**…

In the first paper that Greg and I wrote, we predicted the vaccines would cause an increased emergence of variants of spike protein, altered versions of the virus, under the pressure of the vaccine. Indeed, it looks to me like that's what's happening."

[865] ***Vaccine Acquired Immune Deficiency Syndrome (VAIDS): 'We should anticipate seeing this immune erosion more widely'***
America's Frontline Doctors
December 5, 2021
https://americasfrontlinedoctors.org/news/post/vaccine-acquired-immune-deficiency-syndrome-vaids-we-should-anticipate-seeing-this-immune-erosion-more-widely/

"A Lancet study comparing vaccinated and unvaccinated people in Sweden was conducted among 1.6 million individuals over nine months. It showed that protection against symptomatic COVID-19 declined with time, such that by six months, some of the more vulnerable vaccinated groups were at greater risk than their unvaccinated peers.

Doctors are calling this phenomena in the repeatedly vaccinated **'immune erosion'** or **'acquired immune deficiency'** [*emphasis added*], accounting for elevated incidence of

myocarditis and other post-vaccine illnesses that either affect them more rapidly, resulting in death, or more slowly, resulting in chronic illness.

COVID vaccines are not traditional vaccines. Rather, they cause cells to reproduce one portion of the SARS-CoV-2 virus, the spike protein. The vaccines thus induce the body to create spike proteins. A person only creates antibodies against this one limited portion (the spike protein) of the virus. This has several downstream deleterious effects.

First, these vaccines 'mis-train' the immune system to recognize only a small part of the virus (the spike protein). Variants that differ, even slightly, in this protein are able to escape the narrow spectrum of antibodies created by the vaccines.

Second, the vaccines create 'vaccine addicts,' meaning persons become dependent upon regular booster shots, because they have been 'vaccinated' only against a tiny portion of a mutating virus. Australian Health Minister Dr. Kerry Chant has stated that COVID will be with us forever and people will 'have to get used to' taking endless vaccines. 'This will be a regular cycle of vaccination and revaccination.'

Third, the vaccines do not prevent infection in the nose and upper airways, and vaccinated individuals have been shown to have much higher viral loads in these regions. This leads to the vaccinated becoming 'super-spreaders' as they carry extremely high viral loads.

In addition, the vaccinated become more clinically ill than the unvaccinated. Scotland reported that the infection fatality rate in the vaccinated is 3.3 times the unvaccinated, and the risk of death if hospitalized is 2.15 times the unvaccinated."

[866] ***Why a 4th COVID-19 Shot Likely Won't Provide More Protection***
Healthline
Elizabeth Pratt
January 17, 2022
https://www.healthline.com/health-news/why-a-4th-covid-19-shot-likely-wont-provide-more-protection

"European regulators say giving COVID-19 booster shots too frequently may **weaken immune response** [*emphasis added*].

At a press briefing, experts from the European Medicines Agency (EMA) argued that COVID-19 booster shots should not be given too close together.

'We are rather concerned about a strategy that entangles repeated vaccination within a short term. We cannot really continuously give a booster dose every 3 or 4 months,' Marco Cavaleri, the head of Biological Health Threats and Vaccines Strategy at the EMA, said at the briefing.

'If we have a strategy in which we give boosters, let's say every 4 months approximately, we will end up potentially having a problem with the immune response, and the immune response may end up not being as good as we would like it to be. So we should be careful in not overloading the immune system with repeated immunization,' Cavaleri added.

In addition, researchers in Israel say a fourth COVID-19 shot doesn't appear to produce enough antibodies to prevent infection from the Omicron variant."

[867] ***Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam***
The Lancet
Nguyen Van Vinh Chau, Nghiem My Ngoc, *et al*.
August 10, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

"**Methods**: We studied breakthrough infections among healthcare workers of a major infectious diseases hospital in Vietnam. We collected demographics, vaccination history and results of PCR diagnosis alongside clinical data. We measured SARS-CoV-2 (neutralizing) antibodies at diagnosis, and at week 1, 2 and 3 after diagnosis. We sequenced the viruses using ARTIC protocol.

Findings: … Viral loads of breakthrough Delta variant infection cases were 251 times higher than those of cases infected with old strains detected between March-April 2020…

Interpretation: Breakthrough Delta variant infections are associated with **high viral loads**, prolonged PCR positivity, and **low levels of vaccine-induced neutralizing antibodies**, explaining the transmission between the vaccinated people [*emphasis added*].."

[868] **Video (1m): Commentary from Dr. David Bauer of the Francis Crick Institute**
June 3, 2021
https://www.bitchute.com/video/KP1FfkARcoet/

Bauer: "So the key message from our findings is that we found that recipients of the Pfizer vaccine, those who have had two doses, have about **5-6 fold lower amounts of neutralizing antibodies** [*emphasis added*]. Now these are the sort of 'gold-standard,' private-security antibodies of your immune system, which block the virus from getting into your cells in the first place. So we found that that's less for people with two doses. We also found that for people with only one dose of the Pfizer jab, that they are less likely to have high levels of these antibodies in their blood. And perhaps most importantly for all of us going forward is that we see that the older you are, the lower your levels are likely to be. And the time since you had your second jab, as time goes on, the lower your levels are also likely to be. So that's telling us that we're probably going to be needing to prioritize boosters for more older and more vulnerable people, coming up soon, especially if this new variant spreads."

[869] ***Innate Immune Suppression by SARS-CoV-2 mRNA Vaccinations: The role of G-quadruplexes, exosomes and microRNAs***
Stephanie Seneff, Greg Nigh, Anthony M. Kyriakopoulos, and Peter A McCullough
January 21, 2021
https://www.authorea.com/users/455597/articles/552937-innate-immune-suppression-by-sars-cov-2-mrna-vaccinations-the-role-of-g-quadruplexes-exosomes-and-micrornas?commit=d033a57415da0ca976b27f11d81a4cd604f7fdc7

"**Abstract**: ... In this paper, we present the evidence that vaccination, unlike natural infection, induces a profound impairment in type I interferon signaling, which has diverse adverse consequences to human health. We explain the mechanism by which immune cells release into the circulation large quantities of exosomes containing spike protein along with critical microRNAs that induce a signaling response in recipient cells at distant sites. We also identify potential profound disturbances in regulatory control of protein synthesis and cancer

surveillance. These disturbances are shown to have a **potentially direct causal link** to neurodegenerative disease, myocarditis, immune thrombocytopenia, Bell's palsy, liver disease, impaired adaptive immunity, increased tumorigenesis, and DNA damage [*emphasis added*]. We show evidence from adverse event reports in the VAERS database supporting our hypothesis. We believe a comprehensive risk/benefit assessment of the mRNA vaccines excludes them as positive contributors to public health, even in the context of the Covid-19 pandemic."

[870] **Correspondence: *Implications of antibody-dependent enhancement of infection for SARS-CoV-2 countermeasures***
Nature Biotechnology
Nikolai Eroshenko, Taylor Gill, Marianna K. Keaveney, George M. Church, Jose M. Trevejo, and Hannu Rajaniemi
June 5, 2020
https://www.nature.com/articles/s41587-020-0577-1

"When four different SARS-CoV vaccines developed for human use were tested in mice (two different whole virus vaccines, a recombinant spike protein, and a virus-like particle), they all triggered pulmonary immunopathology upon viral challenge."

Irregular Menstruation, Infertility, and Related Concerns

[871] ***Comirnaty (COVID-19 mRNA Vaccine) Risk Management Plan***
Pfizer, Inc.
November 25, 2021
https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf

"**Table 52. Use in Pregnancy and while Breast Feeding**…

The safety profile of the vaccine is **not known** in pregnant or breastfeeding women [*emphasis added*] due to their initial exclusion from the pivotal clinical study. There may be pregnant women who choose to be vaccinated despite the lack of safety data. It will be important to follow these women for pregnancy and birth outcomes. The **timing of vaccination** in a pregnant woman and the subsequent immune response **may have** varying favourable or **unfavourable impacts on the embryo/foetus**."

[872] ***#Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)***
Pfizer, Inc.
Revised December 22, 2022
https://www.fda.gov/media/153713/download

"INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the 'Vaccine Information Fact Sheet for Recipients and Caregivers' (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Vaccine Information Fact Sheet for Recipients and Caregivers) prior to the individual receiving each dose of the Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- There is an option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are **unknown** [sic]…

11.1 Pregnancy – Risk Summary: … Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are **insufficient to inform vaccine-associated risks in pregnancy** [*emphasis added*].

11.2 Lactation – Risk Summary: Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion."

[873] **Package insert for Comirnaty and Pfizer-BioNTech COVID-19 Vaccine**
Food and Drug Administration (FDA)
Revised August 2021.
https://www.fda.gov/media/151707/download

"**8 Use in Specific Populations**

8.1 Pregnancy: … Available data on COMIRNATY administered to pregnant women are **insufficient to inform vaccine-associated risks** in pregnancy [*emphasis added*]…

8.2 Lactation: It is not known whether COMIRNATY is excreted in human milk. Data are not available to assess the effects of COMIRNATY on the breastfed infant or on milk production/excretion….

13 Nonclinical Toxicology

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility: COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility."

[874] **ADDED since 2/8/2022**
COVID-19 Vaccines While Pregnant or Breastfeeding
Centers for Disease Control and Prevention
Updated October 20, 2022
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

"COVID-19 vaccination is recommended for all people aged 6 months and older. **This includes people who are pregnant, breastfeeding**, trying to get pregnant now, or those who might become pregnant in the future. This also includes infants ages 6 months and older born to people who were vaccinated or had a COVID-19 infection before or during pregnancy."

[875] **ADDED since 2/8/2022**
Decision: Summary of the Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech
Medicines & Healthcare Products Regulatory Agency, UK
Updated December 9, 2022
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine

"**3.4 Toxicology** …

The absence of reproductive toxicity data is a reflection of the speed of development to first identify and select COVID-19 mRNA Vaccine BNT162b2 for clinical testing and its rapid development to meet the ongoing urgent health need. In principle, a decision on licensing a vaccine could be taken in these circumstances without data from reproductive toxicity studies animals, but there are studies ongoing and these will be provided when available. In the context of supply under Regulation 174, it is considered that sufficient reassurance of safe use of the vaccine in pregnant women **cannot be provided at the present time**: however, use in women of childbearing potential could be supported provided healthcare professionals are advised to rule out known or suspected pregnancy prior to vaccination. Women who are breastfeeding should also **not be vaccinated**. These judgements reflect the absence of data

at the present time and do not reflect a specific finding of concern."

[876] **Press briefing (video): Remarks by Dr. Anthony Fauci**
White House COVID-19 Response Team
August 31, 2021
https://youtu.be/ObhlcO5IZqw?t=595

Fauci (starting at 9:55): "I would like to update you now on COVID-19 vaccination and pregnancy. It is very clear now, as I'll show you in a moment, that there are severe, adverse outcomes for mother and baby during COVID-19 infection. Therefore, it is **extremely important** for pregnant women and women planning to get pregnant to get vaccinated."

[877] ***My Cycle Story: A Research Study***
https://mycyclestory.com/
Take the Survey:
https://docs.google.com/forms/d/e/1FAIpQLScbT3nkob17EeoGaW48D5pQ7XYPX4cXuCX_q1fP_rxmA3e2qw/viewform

"**More About Our Study**: We're a collective of concerned physicians, scientists, and citizens on a mission to find answers we can share and demand investigation.

We teamed up with General Genomics to survey the women of the world and turn their stories into data that can be studied.

Key Information About the Survey: You are being asked to participate in a voluntary research study. The purpose of this study is to understand the menstrual experiences of women who have been seeing irregularities and the possible effects of the distribution of the COVID-19 vaccine. Participating in this study will involve completing a secure online survey which takes about 15-20 minutes. Risks related to this research include the potential to feel uncomfortable answering questions about your body and health. Benefits related to this research include being able to share your experiences and contribute to an often-overlooked area of health research.

Purpose of the study: This research study is about your experiences with your period or other menstrual bleeding (such as 'spotting') and associated symptoms out of the ordinary since the beginning of the distribution of a vaccine for COVID-19. Side effects are a common and even important element of the vaccine response, and bleeding patterns can be an important way to understand how our immune systems are activated."

[878] **ADDED since 2/8/2022**
Potential adverse effects of nanoparticles on the reproductive system
Southern Medical University, China
Ruolan Wang, Bin Song, Junrong Wu, Yanli Zhang, Aijie Chen, and Longquan Shao
December 11, 2018
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6294055/

"**Abstract**: With the vigorous development of nanometer-sized materials, nanoproducts are becoming widely used in all aspects of life. In medicine, nanoparticles (NPs) can be used as nanoscopic drug carriers and for nanoimaging technologies. Thus, substantial attention has been paid to the potential risks of NPs. Previous studies have shown that numerous types of

NPs are able to pass certain biological barriers and exert toxic effects on crucial organs, such as the brain, liver, and kidney. Only recently, attention has been directed toward the reproductive toxicity of nanomaterials. NPs can pass through the blood–testis barrier, placental barrier, and epithelial barrier, which protect reproductive tissues, and then accumulate in reproductive organs. **NP accumulation damages organs** (testis, epididymis, ovary, and uterus) by destroying Sertoli cells, Leydig cells, and germ cells, **causing reproductive organ dysfunction** that adversely affects sperm quality, quantity, morphology, and motility or reduces the number of mature oocytes and disrupts primary and secondary follicular development. In addition, NPs can disrupt the levels of secreted hormones, causing changes in sexual behavior. However, the current review primarily examines toxicological phenomena. The molecular mechanisms involved in NP toxicity to the reproductive system are not fully understood, but possible mechanisms include oxidative stress, apoptosis, inflammation, and genotoxicity. Previous studies have shown that NPs can increase inflammation, oxidative stress, and apoptosis and induce ROS, causing damage at the molecular and genetic levels which results in cytotoxicity. This review provides an understanding of the applications and toxicological effects of NPs on the reproductive system."

[879] **ADDED since 2/8/2022**

Accumulation of nanocarriers in the ovary: A neglected toxicity risk?

Journal of Controlled Release — Martin Luther University Halle-Wittenberg, Germany

Andreas Schädlich, Stefan Hoffmann, et al.

February 21, 2012

https://www.sciencedirect.com/science/article/abs/pii/S0168365912000892

"**Abstract**: Several nanocarrier systems are frequently used in modern pharmaceutical therapies. Within this study a potential toxicity risk of all nanoscaled drug delivery systems was found. An accumulation of several structurally different nanocarriers but not of soluble polymers was detected in rodent ovaries after intravenous (i.v.) administration. Studies in different mouse species and Wistar rats were conducted and a **high local accumulation of nanoparticles, nanocapsules and nanoemulsions in specific locations of the ovaries was found in all animals**. We characterised the enrichment by in vivo and ex vivo multispectral fluorescence imaging and confocal laser scanning microscopy. The findings of this study emphasise the role of early and comprehensive in vivo studies in pharmaceutical research. Nanocarrier accumulation in the ovaries may also comprise an important toxicity issue in humans but the results might as well open a new field of targeted ovarian therapies."

Note: The citations below are presented in reverse, chronological order.

[880] **ADDED since 2/8/2022**
COVID-19 vaccine surveillance report — Week 5
UK Health Security Agency
February 2, 2023
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1134076/vaccine-surveillance-report-week-5-2023.pdf

Table 8. Overall vaccine coverage in women giving birth, by month of delivery[1]

Month	Women giving birth	One or more doses by time of delivery	2 or more doses by time of delivery	Unvaccinated at delivery	Unvaccinated who went on to receive doses after pregnancy to 26 August 2022
January 2021	41,949	18 (0.0%)	1 (0.0%)	41,774 (99.6%)	32,271 (77.3%)
February 2021	40,093	83 (0.2%)	0 (0.0%)	39,882 (99.5%)	30,833 (77.3%)
March 2021	44,589	296 (0.7%)	25 (0.1%)	44,173 (99.1%)	33,931 (76.8%)
April 2021	42,467	493 (1.2%)	93 (0.2%)	41,825 (98.5%)	31,850 (76.2%)
May 2021	43,964	1,261 (2.9%)	309 (0.7%)	42,542 (96.8%)	31,625 (74.3%)
June 2021	43,723	4,369 (10.0%)	656 (1.5%)	39,219 (89.7%)	27,832 (71.0%)
July 2021	47,393	7,717 (16.3%)	2,203 (4.6%)	39,497 (83.3%)	26,493 (67.1%)
August 2021	46,149	10,486 (22.7%)	6,129 (13.3%)	35,488 (76.9%)	22,208 (62.6%)
September 2021	46,710	15,101 (32.3%)	10,519 (22.5%)	31,433 (67.3%)	17,992 (57.2%)
October 2021	46,196	19,211 (41.6%)	14,655 (31.7%)	26,801 (58.0%)	13,689 (51.1%)
November 2021	42,917	20,896 (48.7%)	16,482 (38.4%)	21,860 (50.9%)	8,864 (40.5%)
December 2021	41,578	22,372 (53.8%)	18,048 (43.4%)	19,033 (45.8%)	5,634 (29.6%)
January 2022	39,331	23,449 (59.6%)	19,971 (50.8%)	15,739 (40.0%)	2,776 (17.6%)
February 2022	36,348	23,938 (65.9%)	21,043 (57.9%)	12,254 (33.7%)	1221 (10.0%)
March 2022	38,702	26,936 (69.6%)	23,957 (61.9%)	11,625 (30.0%)	611 (5.3%)
April 2022	37,539	26,961 (71.8%)	24,324 (64.8%)	10,426 (27.8%)	330 (3.2%)
May 2022	38,345	28,023 (73.1%)	25,645 (66.9%)	10,187 (26.6%)	199 (2.0%)
June 2022	37,037	27,029 (73.0%)	24,933 (67.3%)	9,855 (26.6%)	96 (1.0%)

[1] 2,778 women could not be matched with a NIMS record. Their vaccine status is therefore unknown and they are excluded from these coverage figures.

[881] **ADDED since 2/8/2022**
COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function
Truth for Health Foundation
James A. Thorp, Claire Rogers, *et al*.
December 30, 2022
https://www.preprints.org/manuscript/202209.0430/v2

"**Objectives**: Assess rates of adverse events (AE) after COVID-19 vaccines experienced by women of reproductive age, focusing on pregnancy and menstruation, using data collected by the US Centers for Disease Control and Prevention (CDC) Vaccine Adverse Events Reporting System (VAERS) database.

Design: Population-based retrospective cohort study…

Results: COVID-19 vaccines, when compared to the Influenza vaccines, are associated with a significant increase in AE with all proportional reporting ratios of > 2.0: menstrual abnormalities, miscarriage, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal arrhythmias, fetal cardiac arrest, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, fetal placental thrombosis, low amniotic fluid, preeclampsia, premature delivery, preterm premature rupture

of membrane, fetal death/stillbirth, and premature baby death (all p values were much smaller than 0.05). When normalized by time-available, doses-given, or persons-received, all COVID-19 vaccine AE far exceed the safety signal on all recognized thresholds.

Conclusions: Pregnancy complications and menstrual abnormalities are significantly more frequent following COVID-19 vaccinations than Influenza vaccinations. A **worldwide moratorium on the use of COVID-19 vaccines in pregnancy is advised** until randomized prospective trials document safety in pregnancy and long-term follow-up in offspring."

[882] **ADDED since 2/8/2022**

EU regulator recommends adding heavy periods to side effects of mRNA COVID shots

Reuters
Natalie Grover
October 28, 2022
https://www.reuters.com/business/healthcare-pharmaceuticals/ema-panel-lists-heavy-menstrual-bleeding-side-effect-moderna-pfizer-shots-2022-10-28/

"A European Medicines Agency (EMA) committee on Friday recommended adding heavy menstrual bleeding to the list of side effect of mRNA COVID-19 vaccines made by Moderna (MRNA.O), as well as Pfizer (PFE.N) and its partner BioNTech (22UAy.DE).

Reports of heavy periods - bleeding characterised by increased volume and/or duration that interferes with the quality of life - have been observed during clinical trials, from cases in the real world and in medical literature, the EMA said…

A Moderna spokesperson said the company was aware of reports linking its vaccine to **dysmenorrhea**, or pain associated with menstruation."

[883] **ADDED since 2/8/2022**

Investigating trends in those who experience menstrual bleeding changes after SARS-CoV-2 vaccination

Science Advances — University of Illinois
Katharine M.N. Lee, Eleanor J. Junkins, *et al*.
July 15, 2022
https://www.science.org/doi/10.1126/sciadv.abm7201

"**Abstract**: Early in 2021, many people began sharing that they experienced unexpected menstrual bleeding after SARS-CoV-2 inoculation. We investigated this emerging phenomenon of changed menstrual bleeding patterns among a convenience sample of currently and formerly menstruating people using a web-based survey. In this sample, 42% of people with regular menstrual cycles **bled more heavily than usual**, while 44% reported no change after being vaccinated. Among respondents who typically do not menstruate, 71% of people on long-acting reversible contraceptives, 39% of people on gender-affirming hormones, and 66% of postmenopausal people reported **breakthrough bleeding**."

[884] **ADDED since 2/8/2022**

Fertility declines near the end of the COVID-19 pandemic: Evidence of the 2022 birth declines in Germany and Sweden

Stockholm University
Martin Bujard and Gunnar Andersson
June 9, 2022
https://su.figshare.com/articles/preprint/Fertility_declines_near_the_end_of_the_COVID-19_pandemic_Evidence_of_the_2022_birth_declines_in_Germany_and_Sweden/20975611

> "Following the onset of the COVID-19 pandemic, several countries faced short-term fertility declines in 2020 and 2021, a development which did not materialize in Scandinavian and German-speaking countries. However, more recent birth statistics show a steep fertility decline in the aftermath of the pandemic in 2022. In this study, we aim to provide data on the unexpected birth decline in 2022 in Germany and Sweden and relate these data to pandemic-related contextual developments which could have influenced the post-pandemic fertility development. We rely on monthly birth statistics and present seasonally adjusted monthly Total Fertility Rates (TFR) for Germany and Sweden. We relate the nine-months lagged fertility rates to contextual developments regarding COVID-19 mortality and morbidity, unemployment rates, and COVID-19 vaccinations. We show that the seasonally adjusted monthly TFR of Germany dropped from 1.5-1.6 in 2021 to 1.3-1.4 in early 2022, a decline of about **14%**. In Sweden, the corresponding TFR dropped from about 1.7 in 2021 to 1.5-1.6 in early 2022, a decline of almost **10%**. There is no association of the fertility trends with changes in unemployment, infection rates, or COVID-19 deaths. However, **there is a strong association between the onset of vaccination programmes and the fertility decline nine months after of this onset**. The fertility decline in the first months of 2022 in Germany and Sweden is remarkable. Common explanations of fertility change during the pandemic do not apply in its aftermath. The association between the onset of mass vaccinations and subsequent fertility decline indicates that people adjusted their behaviour to get vaccinated before becoming pregnant, as societies were opening up with post-pandemic life conditions. Our study provides novel information on fertility declines in countries previously not affected by any COVID-19 baby bust. We provide a first appraisal of the COVID-19-fertility nexus in the immediate aftermath of the pandemic."

[885] **ADDED since 2/8/2022**

Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors

Andrology
Itai Gat, Alon Kedem, *et al.*
June 6, 2022
https://onlinelibrary.wiley.com/doi/10.1111/andr.13209

> "**Objective**: To investigate the effect of covid-19 BNT162b2 (Pfizer) vaccine on semen parameters among semen donors (SD)…
>
> **Discussion**: This longitudinal study focused on SD demonstrates selective temporary sperm concentration and TMC [*total motile count*] deterioration 3 months after vaccination followed by later recovery verified by diverse statistical analyses."

[886] **ADDED since 2/8/2022**

COVID-19 and the surge in Decidual Cast Shedding

The Gazette of Medical Sciences

Tiffany Parotto, James A. Thorp, *et al*.

April 21, 2022

https://www.thegms.co/publichealth/pubheal-ra-22041401.pdf

"**Background**: The purpose of this study is to report on the unprecedented rise in decidual cast shedding (DCS) that occurred in 2021. DCS is historically a rare gynecological event, with less than 40 cases reported in the medical literature over the last 109 years. Previous journal articles on DCS were usually case studies; population prevalence data is non-existent.

Methods: The MyCycleStory SM survey was distributed via social media from May 16th, 2021, through December 31, 2021. The total sample size for analysis was 6049 with 89.1% of the participants responding within the first 3.5 months of the 7.5 months duration of the study. In parallel to the survey study, a Google Trends search was completed for search frequencies of relevant keyword terms including "decidual cast" and "decidual cast covid vaccine."

Results: In the survey, 292 women (4.83 % of the sample) reported having experienced DCS. The mean age of these predominantly non-Hispanic white women was 36.1 ± 0.5 (SEM) years. Eleven percent were taking hormonal contraceptives, 94.3% considered themselves healthy and 96.2% reported that menstrual irregularities started in 2021. According to Google metadata, search terms for "decidual cast shedding" substantially increased during the months of April, May, and June 2021. These peaks in searches represented a 2000% increase over the first quarter of 2021.

Conclusions: There was a significant increase in self-reported DCS in the latter part of 2021 compared to all pre-pandemic cases…

Discussion: The most striking finding of this study is the remarkable incidence of decidual cast shedding (DCS) among the survey respondents, which identified **292 respondents noting a DCS event** over 7.5 months in 2021. **In comparison, all previously published medical literature spanning 109 years describes less than 40 cases**. Undoubtedly, this is a significant surge in DCS events…

Here, we speculate on possible causes of this DCS phenomenon. One hypothesis is that **the COVID-19 vaccine interrupts the complex balance of ovulation orchestrated by the hypothalamic-pituitary-ovarian axis and thus produces anovulatory bleeding disorders**. It is known from COVID-19 mRNA vaccine documents that **there is concentration of the nanolipid particles and the mRNA cargo in the ovaries**. This produces significant inflammatory response in the ovaries and could contribute to menstrual abnormalities, although there are many other potential mechanisms that could be involved.

COVID-19 vaccination is associated with both micro- and macro-arterial and venous thromboembolism. An unusual clotting process associated with fibrin deposition appears as a white 'tissue-like' material in vaccine recipients, and embalmers have observed very extensive and durable white clots that are removed post-mortem in the embalming process. Figure 6 depicts multiple clots extracted intact by an embalmer who describes the blood as 'abnormally thickened and sticky' and difficult to wipe off gloves or the embalming table. He further notes that the extracted blood clots are very durable and difficult to break up. Embalmers have

apparently never seen this phenomenon prior to the pandemic. We speculate that one potential explanation of the surge in reports of decidual cast shedding could represent a similar appearing tissue-like substance that is composed of fibrin-laden clot rather than a simple decidual cast."

[887] ***Spontaneous Abortions and Policies on COVID-19 mRNA Vaccine Use During Pregnancy***
Institute for Pure and Applied Knowledge (IPAK)
Aleisha R. Brock and Simon Thornley
November 2021
https://www.thelastamericanvagabond.com/wp-content/uploads/2021/10/21-11-Brock-Thornley.pdf

"**Abstract**: … The use of mRNA vaccines in pregnancy is now generally considered safe for protection against COVID-19 in countries such as New Zealand, USA, and Australia. However, the influential CDC-sponsored article by Shimabukuro et al. (2021) used to support this idea, on closer inspection, provides little assurance, particularly for those exposed in early pregnancy. The study presents falsely reassuring statistics related to the risk of spontaneous abortion in early pregnancy, since the majority of women in the calculation were exposed to the mRNA product after the outcome period was defined (20 weeks' gestation).

In this article, we draw attention to these errors and recalculate the risk of this outcome based on the cohort that was exposed to the vaccine before 20 weeks' gestation. Our re-analysis indicates a **cumulative incidence of spontaneous abortion 7 to 8 times higher** than the original authors' results ($p < 0.001$) and the typical average for pregnancy loss during this time period [*emphasis added*]. In light of these findings, key policy decisions have been made using unreliable and questionable data. We conclude that the claims made using these data on the safety of exposure of women in early pregnancy to mRNA-based vaccines to prevent COVID-19 are unwarranted and recommend that those policy decisions be revisited."

[888] **Video (8m): Interview with Dr. Michael Yeadon on "Fertility & the Jab"**
From *Planet Lockdown* (documentary)
Michael Yeadon, former chief scientist and vice-president of Pfizer's allergy and respiratory research unit in Sandwich, Kent
October 3, 2021
https://rumble.com/vnpw33-michael-yeadon-fertility-and-the-jab-planet-lockdown.html

"We [*Dr. Wolfgang Wodarg and Yeadon*] did have another concern, as well. And that was that… parts of the virus [*COVID-19*] are similar to the human protein called syncitins. Now syncitins are released in the pregnant uterus and the pregnant womb, and are required for the formation of and maintenance of the placenta. In other words, if you don't have syncitins working properly, you can't form a placenta around and support the growing embryo and then a baby. And our concern was that … when you vaccinate a person, they may make antibodies or other immune responses against that piece of the vaccine, and we worry that that might lead, in a low percentage of cases, to an attack on the placenta. And as far as we're aware, none of the companies have done any research to eliminate that possibility, either through animal experiments or through measuring the binding of antibodies to human syncitins.

So I am not saying that if you take these vaccines, it will cause infertility. But I will say that none of the manufacturers should give you any assurances whatsoever that it won't because

they have not bothered to measure whether the similarity is enough to produce, on any occasions, any antibody at all that might bind to your own syncitin hormone. And if it does, yeah, it could stop you getting pregnant or prevent your placenta from functioning properly. That's the concern…

There is no question that syncitin and stretches of the virus are… homologous. They come from the same family and I think that changes things. It means they might fold in ways that are similar in three dimensions…

I'm not interested in whether it's a likelihood, I was demanding a certainty that it didn't happen, right? I'm looking at this from a toxicological principle. I want you to experimentally exclude the possibility that in anyone, antibodies to the vaccine could bind to syncitin. I want you to actually show me that these are so separated that it can't occur. Because if you can't say that, you're exposing people, without telling them, to a potential risk of damaging fertility. And I think that's completely unethical, don't you?"

[889] **ADDED since 2/8/2022**

Potential toxicity of nanoparticles on the reproductive system animal models

Journal of Reproductive Immunology — Iran University of Medical Sciences

Marziyeh Ajdary, Fariborz Keyhanfar, *et al*.

September 25, 2021

https://www.sciencedirect.com/science/article/abs/pii/S0165037821001145

"**Abstract**: Over the past two decades, nanotechnology has been involved in an array of applications in various fields, including diagnostic kits, disease treatment, drug manufacturing, drug delivery, and gene therapy. But concerns about the toxicity of nanoparticles have greatly hindered their use; also, due to their increasing use in various industries, all members of society are exposed to the toxicity of these nanoparticles. Nanoparticles have a negative impact on various organs, including the reproductive system. They also can **induce abortion in women, reduce fetal growth and development, and can damage the reproductive system and sperm morphology in men**. In some cases, it has been observed that despite the modification of nanoparticles in composition, concentration, and method of administration, there is still damage to the reproductive organs. Therefore, understanding how nanoparticles affect the reproductive system is of very importance. In several studies, the nanoparticle toxicity effect on the genital organs has been investigated at the clinical and molecular levels using the in vivo and in vitro models. This study reviews these investigations and provides important data on the toxicity, hazards, and safety of nanoparticles in the reproductive system to facilitate the optimal use of nanoparticles in the industry."

[890] ***Why didn't doctors listen to women about the link between Covid vaccines and periods?***
The Telegraph
Caroline Criado-Perez
September 17, 2021
https://www.msn.com/en-ph/health/medical/why-didnt-doctors-listen-to-women-about-the-link-between-covid-vaccines-and-periods/ar-AAOxleX

> "This week, a study in the BMJ revealed that almost 35,000 British women have reported that following their vaccination against Covid, they have experienced more painful and/or irregular periods. A month later, they were back to normal…
>
> This study is not the first we've heard of period disruption being linked to the jab. Ever since the vaccine roll-out began women have been all over social media, talking about how the vaccine seemed to have an impact on their menstrual cycle.
>
> For most of these women, their vaccine shot was followed by a late period or a particularly heavy period. Other women experienced breakthrough bleeding (when you bleed outside of your period), some women whose contraception meant they had not had a period for years suddenly had to rush out for tampons. All of these women came to social media for advice or reassurance. But until this study, there has been little on offer, highlighting how little anyone has thought to consider the chance of a connection…
>
> As with most clinical studies, the **Covid-19 vaccine trials did not investigate menstrual cycle effects** – in fact, in many trials women are wholesale excluded because of potential menstrual cycle effects [*emphasis added*]…
>
> [E]nough women have now reported menstrual cycle effects that the issue has become impossible to ignore: the US National Institute of Health (NIH) has now allocated $1.67 million to research a possible link between COVID-19 vaccines and the menstrual cycle, as well as how long any impact might last. To put this in context, the NIH has to date spent almost $4.9 billion on COVID-19 research."

[891] ***Menstrual changes after covid-19 vaccination***
British Medical Journal
Victoria Male
September 16, 2021
https://www.bmj.com/content/374/bmj.n2211

> "Changes to periods and unexpected vaginal bleeding are not listed, but primary care clinicians and those working in reproductive health are increasingly approached by people who have experienced these events shortly after vaccination. **More than 30 000 reports of these events** had been made to MHRA's yellow card surveillance scheme for adverse drug reactions by 2 September 2021, across all covid-19 vaccines currently offered [*emphasis added*]…
>
> We are still awaiting definitive evidence, but in the interim how should clinicians counsel those who have experienced these effects? Initially, they should be encouraged to report any changes to periods or unexpected vaginal bleeding to the MHRA's yellow card scheme…
>
> One important lesson is that the effects of medical interventions on menstruation should not be an afterthought in future research."

[892] ***People said the covid vaccine affected their periods. Now more than $1.6 million will go into researching it.***
The Lily
Julianne McShane
September 7, 2021
https://www.thelily.com/people-said-the-covid-vaccine-affected-their-periods-now-more-than-16-million-will-go-into-researching-it/

> "The National Institutes of Health awarded funding to researchers at five institutions to study possible links…
>
> 'Our goal is to provide menstruating people with information, mainly as to what to expect, because I think that was the biggest issue: Nobody expected it to affect the menstrual system, because the information wasn't being collected in the early vaccine studies,' said Bianchi [*NIH*], who credited The Lily's early coverage of the issue, in April, with first making her and her staff aware of it…
>
> The NIH funding 'signifies that they're recognizing that there's an important gap in our understanding of how vaccines influence menstrual health and ultimately reproductive health,' according to Leslie Farland, an assistant professor in the department of epidemiology and biostatistics at the University of Arizona's College of Public Health.
>
> Earlier this year, a number of women and menstruators took to Facebook groups and Reddit threads to share their accounts of their post-vaccination periods. A Twitter thread authored by Kate Clancy, an associate professor of anthropology who studies reproductive justice at the University of Illinois, attracted **more than 1,000 responses from menstruators about how their cycles were altered following their vaccinations** [*emphasis added*] — another source of information that Bianchi said was crucial in shaping the agency's understanding of the prevalence of the issue."

[893] ***Researchers studying reported menstrual changes after COVID-19 vaccination***
WBRC (Alabama)
Morgan Hightower
July 8, 2021
https://www.wbrc.com/2021/07/08/researchers-studying-reported-menstrual-changes-after-covid-19-vaccination/

> "'When we were going through ethics approval, Katie and I had a discussion about how many people we anticipated would participate and the number we put in was 500 and that was being optimistic,' said Kate Clancy, PhD, Director of Graduate Studies, Associate Professor of Anthropology, University of Illinois. 'We hit 500, I think, in the first couple of hours and, in fact, were in the thousands within 24 hours [*emphasis added*].'…
>
> 'It [*menstrual change*] also isn't listed as a side effect in part because **nobody thought to ask about it during the trials** [*emphasis added*], so they only list the trial they expect to happen, or that get reported by a lot of folks who get vaccinated, and this sort of fell between the cracks of the vaccine trials, if it's a side effect for people in response to the vaccine, it just wasn't considered during those processes.'"

[894] ***Assessment report: COVID-19 Vaccine Moderna***
European Medicines Agency
March 11, 2021
https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf

"**Reproduction Toxicity**

A GLP-compliant reproductive and developmental toxicology (DART) study with mRNA-1273 has been conducted in female Sprague Dawley CD rats.

IM [*intramuscular*] administrations of mRNA-1273 to female SD 1 rats at the human clinical dose, twice before mating and twice during gestation, was associated with non-adverse effects including thin fur cover, swollen hindlimbs and limited usage of the hindlimb. However, there were no mRNA-1273-related effects on female fertility, embryo-foetal or post-natal survival, growth or development in the F1 offspring. The mRNA-1273-related non-adverse effects were limited to an increase in the number of foetuses with common skeletal variations of 1 or more rib nodules and 1 or more wavy ribs, with no effect on the viability and growth on the F1 generation pups.

In this study, no vaccine dose was administered during the early organogenesis, to address the direct embryotoxic effect of the components of the vaccine formulation. However, such a risk is considered low in humans, given the non-live organism nature of mRNA-1273 and the low risk of genotoxic effect of SM-102-containing LNP in humans. The overall pregnancy index was numerically lower in mRNA-1273 vaccinated female rats (**84.1%**), compared to control animals (**93.2%**) [*emphasis added*], but remains within the Test Facility's historical control range (low range being 75%)."

Shingles (*herpes zoster*) and Chickenpox (*herpes varicella*)

Note: The citations below are presented in reverse, chronological order.

[895] **ADDED since 2/8/2022**
Persistent varicella zoster virus infection following mRNA COVID-19 vaccination was associated with the presence of encoded spike protein in the lesion
Journal of Cutaneous Immunology and Allergy — Kochi University, Japan
Mayuko Yamamoto, Misaki Kase, *et al*.
August 25, 2022
https://onlinelibrary.wiley.com/doi/10.1002/cia2.12278

> "**Introduction**: Global pandemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or COVID-19), which was spread from China in 2019, urged development of COVID-19 vaccines. Until now, a number of cutaneous reactions after COVID-19 vaccination has been reported worldwide, including injection site reaction or so called COVID arm, urticarial reaction, morbilliform rash, vesicopapular lesions, pityriasis rosea-like lesion, purpura, vasculitis, thrombus, ulcer, and reactivation of herpesviruses.
>
> Previous study revealed that the most frequent skin reactions were COVID arm in women (38.1%) and varicella zoster virus (VZV) reactivation in men (20%). The underlying pathomechanism for the mRNA COVID-19 vaccination-associated skin reactions (hereafter referred to as CVSRs) largely remains unknown… Here, we present a case of persistent VZV infection after COVID-19 vaccination."

[896] **ADDED since 2/8/2022**
Can SARS-CoV-2 vaccine increase the risk of reactivation of Varicella zoster? A systematic review
Journal of Cosmetic Dermatology
Harduj D, Desaum Kamal Sharma, *et al*.
October 31, 2021
https://onlinelibrary.wiley.com/doi/10.1111/jocd.14521

> "**Objective**: To describe the demographic, clinical, morphological characteristics, outcomes, and timing of development of herpes zoster to the various COVID-19 vaccines. And to identify on whether COVID-19 vaccine has temporal relationship between development of herpes zoster (HZ).
>
> **Methods**: We have performed a systemic review of articles from PubMed and Embase...
>
> **Results**: A total of 54 cases consisting of 27 male and 27 female patients have been reported. There were cases with known risk factors for herpes zoster, which included age more than 50 years (n = 36), immunological disorders (n = 10), chronic disease (n = 25), metabolic disorder (n = 13), malignancy (n = 4), and psychiatric disorder (n = 2). The mean (SD) period between development of herpes zoster and COVID-19 vaccination was 7.64 (6.92) days. Majority of the cases were from the high-income and/or middle-income countries. 86.27% of the cases of HZ were reported **due to mRNA vaccine**. Thirty-six patients 36/45 (80%) developed herpes zoster following the priming dose of COVID-19 vaccine among those who received mRNA vaccine...

4.1 Is there a medical or biological basis for an increased risk of COVID-19 vaccine-induced HZ?

Several theories can be postulated to explain the relationship between development of herpes zoster and COVID-19 vaccines. Age was found to be the major risk factor for the development of HZ partly due to age-related decline in cell-mediated immune responses to VZV, whereas disease-related immunocompromise is another risk factor including such as HIV infection, iatrogenic immunocompromission, physical trauma, or comorbid conditions such as malignancy or chronic kidney or liver disease. Studies have reported cross-reactivity between spike protein and self-antigen may lead to development of immune-mediated disorders in COVID-19 patients in the long run. The authors hypothesized that similar response can happen following COVID-19 vaccine. Toll-like receptors (TLR) stimulation of innate immunity might be the connection between COVID-19 vaccine and HZ development. The stimulation of these receptors has been related to the reactivation of VZV, allowing the latent virus to remain dormant in the afflicted people. The **COVID-19 immunization may lead to the production of type I IFNs** [*interferons*] **and other inflammatory cytokines**, activating T- and B-cell immunity and negatively affecting antigen expression, resulting in herpes zoster reactivation. The peak of antigen expression is determined by the administration method and vaccine composition, which is another approach to modulate the immune response."

[897] ***Herpes zoster after COVID vaccination***
International Journal of Infectious Diseases
C.S. van Dam, I. Lede, et al.
October 1, 2021
https://www.ijidonline.com/article/S1201-9712(21)00681-0/fulltext

"**Abstract**: … Our case report describes two adults developing herpes zoster after vaccination with tozinameran (the Pfizer-BioNTech COVID-19 mRNA vaccine). A possible cause for this reaction is a **transient lymphocytopenia that occurs after the vaccination** [*emphasis added*]."

From the NIH: "Lymphocytopenia is a disorder in which your blood doesn't have enough white blood cells called lymphocytes. These cells are made in the bone marrow along with other kinds of blood cells. Lymphocytes help protect your body from infection. Low numbers of lymphocytes can raise your risk of infection."
https://www.nhlbi.nih.gov/health-topics/lymphocytopenia

[898] ***Reactivation of Varicella Zoster Virus after Vaccination for SARS-CoV-2***
Multidisciplinary Digital Publishing Institute (MDPI)
Mina Psichogiou, Michael Samarkos, Nikolaos Mikos, and Angelos Hatzakis
June 1, 2021
https://www.mdpi.com/2076-393X/9/6/572/htm

"**Abstract**: Seven immunocompetent patients aged > 50 years old presented with herpes zoster (HZ) infection in a median of 9 days (range 7–20) after vaccination against SARS-CoV-2. The occurrence of HZ within the time window 1–21 days after vaccination defined for increased risk and the reported T cell-mediated immunity involvement suggest that COVID-19 vaccination is a **probable cause** of HZ. These cases support the importance of continuing assessment of vaccine safety during the ongoing massive vaccination for the COVID-19 pandemic and encourage reporting and communication of any vaccination-associated adverse event."

[899] ***Herpes zoster following BNT162b2 mRNA COVID-19 vaccination in patients with autoimmune inflammatory rheumatic diseases: a case series***
Rheumatology
Victoria Furer, Devy Zisman, Adi Kibari, Doron Rimar, Yael Paran, and Ori Elkayam
April 13, 2021
https://academic.oup.com/rheumatology/advance-article/doi/10.1093/rheumatology/keab345/6225015

"**Objectives**: As global vaccination campaigns against COVID-19 disease commence, vaccine safety needs to be closely assessed. The safety profile of mRNA-based vaccines in patients with autoimmune inflammatory rheumatic diseases (AIIRD) is **unknown**. The objective of this report is to raise awareness of reactivation of herpes zoster (HZ) following the BNT162b2 mRNA vaccination in patients with AIIRD (autoimmune inflammatory rheumatic diseases)…

Conclusion: Epidemiologic studies on the safety of the mRNA-based COVID-19 vaccines in patients with AIIRD are needed to clarify the association between the BNT162b2 mRNA vaccination and reactivation of zoster."

Relapse of Prior Conditions

Note: The citations below are presented in reverse, chronological order.

[900] **ADDED since 2/8/2022**
A Population-Based Analysis of the Risk of Glomerular Disease Relapse after COVID-19 Vaccination
Journal of the American Society of Nephrology — Ottawa Hospital Research Institute
Mark Canney, Mohammad Atiquzzaman, *et al*.
November 30, 2022
https://jasn.asnjournals.org/content/33/12/2247

> "**Significance Statement**: Several reports have described glomerular disease relapse after coronavirus disease 2019 (COVID-19) vaccination, but without proper controls, determining whether this association is real or due to chance is not possible. In this population-level cohort of 1105 adult patients with stable glomerular disease, a first dose of a COVID-19 vaccine was not associated with relapse risk; however, receiving a subsequent vaccine dose was associated with a **two-fold higher risk of relapse**."

[901] **ADDED since 2/8/2022**
Case Report: Cytomegalovirus Reactivation and Pericarditis Following ChAdOx1 nCoV-19 Vaccination Against SARS-CoV-2
Frontiers in Immunology — University Medical Center Göttingen
Marlene Plüß, Kemal Mese, *et al*.
January 18, 2022
https://www.frontiersin.org/articles/10.3389/fimmu.2021.784145/full

> "As the coronavirus disease 2019 (COVID-19) pandemic is ongoing and new variants of severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) are emerging, there is an urgent need for vaccines to protect individuals at high risk for complications and to potentially control disease outbreaks by herd immunity. Surveillance of rare safety issues related to these vaccines is progressing, since more granular data emerge about adverse events of SARS-CoV-2 vaccines during post-marketing surveillance. **Varicella zoster virus** (VZV), **Epstein-Barr virus** (EBV) and **cytomegalovirus** (CMV) **reactivation** has already been reported in COVID-19 patients. In addition, adverse events after SARS-CoV-2 mRNA vaccination have also been in the context of varicella zoster virus (VZV) reactivation and directly associated with the mRNA vaccine. We present the first case of **CMV reactivation** and **pericarditis** in temporal association with SARS-CoV-2 vaccination, particularly adenovirus-based DNA vector vaccine ChAdOx1 nCoV-19 against SARS-CoV-2. After initiation of antiviral therapy with oral valganciclovir, CMV viremia disappeared and clinical symptoms rapidly improved. Since huge vaccination programs are ongoing worldwide, post-marketing surveillance systems must be in place to assess vaccine safety that is important for the detection of any events. In the context of the hundreds of millions of individuals to be vaccinated against SARS-CoV-2, a potential causal association with **CMV reactivation** may result in a considerable number of cases with potentially severe complications."

Adverse Reactions - Other

Note: The citations below are presented in reverse, chronological order.

[902] **ADDED since 2/8/2008**
SARS-CoV-2 vaccination can elicit a CD8 T-cell dominant hepatitis
Journal of Hepatology — University of Freiburg, Germany
Tobias Boettler, Benedikt Csernalabics, *et al*.
April 21, 2022
https://www.sciencedirect.com/science/article/pii/S0168827822002343

> "**Lay Summary**: Liver inflammation is observed during SARS-CoV-2 infection but can also occur in some individuals after vaccination and shares some typical features with autoimmune liver disease. In this report, we show that highly activated T cells accumulate and are evenly distributed in the different areas of the liver in a patient with liver inflammation following SARS-CoV-2 vaccination. Moreover, within the population of these liver-infiltrating T cells, we observed an enrichment of T cells that are reactive to SARS-CoV-2, suggesting that these vaccine-induced cells can contribute to liver inflammation in this context."

[903] **ADDED since 2/8/2008**
Covid-19: Pfizer-BioNTech vaccine is "likely" responsible for deaths of some elderly patients, Norwegian review finds
British Medical Journal
Ingrid Torjesen
May 27, 2021
https://www.bmj.com/content/373/bmj.n1372

> "The Pfizer-BioNTech covid-19 vaccine is "likely" to have been responsible for at least 10 deaths of frail elderly people in nursing homes in Norway, an expert review commissioned by the Norwegian Medicines Agency has concluded.
>
> The expert group was established at the end of February 2021 to look into the cause of the first 100 reported deaths of nursing home residents who had received the Pfizer-BioNTech vaccine…
>
> The review reported on 19 May and concluded that a causal link between the Pfizer-BioNTech vaccine and death was considered 'likely' in 10 of the 100 cases, 'possible' in 26 cases, and 'unlikely' in 59 cases. The remaining five were deemed 'unclassifiable.'
>
> While emphasising considerable uncertainty around its conclusions, the expert group acknowledged a risk that adverse reactions to the vaccines among very frail patients could initiate a cascade of complications, which in the worst case scenario could lead to earlier death…
>
> The group noted that more thorough assessment of the benefits and risks of vaccination could have been made for some very frail elderly people, particularly during the first few weeks of the vaccine's use. People with a very short life expectancy have little to gain from being vaccinated, it said, noting a genuine risk that the time of death will be brought forward and that they will experience adverse reactions to the vaccine in the last days of their life.

The benefits of vaccination for very frail people with very short life expectancy should therefore be carefully assessed against the associated risks, and **it may often be better not to vaccinate**, the group recommended."

[904] **Research Letter: *Acute Allergic Reactions to mRNA COVID-19 Vaccines***
JAMA (Massachusetts General Hospital)
Kimberly G. Blumenthal, Lacey B. Robinson, *et al*.
March 8, 2021
https://jamanetwork.com/journals/jama/fullarticle/2777417

"**Results**: Of 64 900 employees who received their first dose of a COVID-19 vaccine... Acute allergic reactions were reported by **1365 employees overall (2.10%** [95% CI, 1.99%-2.22%]), more frequently with the Moderna vaccine compared with Pfizer-BioNTech (2.20%… vs 1.95%)… Anaphylaxis was confirmed in 16 employees (0.025%)"

COVID-19 Protocols, Prophylactics, and Treatments

Treatment Protocols for COVID-19

[905] ***Treatment Protocols***
C19Protocols
August 22, 2021
https://c19protocols.com/

[906] ***Prevention and Treatment Protocols for COVID-19***
Front Line COVID-19 Critical Care (FLCCC) Alliance
https://covid19criticalcare.com/covid-19-protocols/

[907] ***The Zelenko Protocol***
https://faculty.utrgv.edu/eleftherios.gkioulekas/zelenko/index.html

[908] ***The Fleming Method***
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_cfd91d7e664b4e479b56652cbf246145.pdf

[909] ***MATH+ protocol for the treatment of SARS-CoV-2 infection: the scientific rationale***
Expert Review of Anti-infective Therapy
Paul E. Marik, Pierre Kory, Joseph Varon, Jose Iglesias, and G. Umberto Meduri
August 18, 2020
https://www.tandfonline.com/doi/full/10.1080/14787210.2020.1808462

> "**Conclusions**: COVID-19 disease progresses through a number of phases, each with a unique treatment approach. There is no 'silver bullet' to cure COVID-19. The pulmonary phase of COVID-19 is a treatable disease; it is inappropriate to limit therapy to 'supportive care' alone. The MATH + protocol consists of multiple drugs that have synergistic and overlapping biological effects that are safe, cheap, and readily available and are likely to significantly reduce the morbidly and mortality of this disease. It is likely that the MATH + protocol will be refined and evolve over time as new therapeutic agents are demonstrated to improve the outcome of this devastating disease."

Note: The citations below are presented in reverse, chronological order.

[910] **ADDED since 2/8/2022**
Early Ambulatory Multidrug Therapy Reduces Hospitalization and Death in High-Risk Patients with SARS-CoV-2 (COVID-19)
International Journal of Innovative Research in Medical Science — Baylor University
Brian C. Procter, Casey Ross, *et al*.
March 17, 2021
https://ijirms.in/index.php/ijirms/article/view/1100

"**Background**: There is an emergency need for early ambulatory treatment of COVID-19 in acutely ill patients in an attempt to reduce disease progression and the risks of hospitalization and death. Methods and Results: We recently reported results on 320 high-risk (age > 50 with ≥ 1 comorbidity) COVID-19 cases and have updated our results with 549 additional cases in the period ending December 16, 2020. Our protocol utilizes at least two agents with antiviral activity against SARS-CoV-2 (zinc, hydroxychloroquine, ivermectin) and one antibiotic (azithromycin, doxycycline, ceftriaxone) along with inhaled budesonide and/or intramuscular dexamethasone. Albuterol nebulizer, inhaled budesonide, intravenous volume expansion with supplemental parenteral thiamine 500 mg, magnesium sulfate 4 grams, folic acid 1 gram, vitamin B12 1 mg, are administered to severely ill patients who either present or return to the clinic with severe symptoms. In period 1 (April-September, 2020) 6/320 (1.9%) and 1/320 (0.3%) patients were hospitalized and died, respectively. In period 2, (September-December, 2020) 14/549 (2.6%) and 1/549 (0.18%) were hospitalized and died, respectively. For comparison, we used the Cleveland Clinic COVID-19 hospitalization calculator and based on average age and comorbidities the expected rate of hospitalization for both periods was 18.5%. The cumulative mortality among confirmed and suspected COVID-19 in Collin, Dallas, Denton, and Tarrant counties was 0.76, 1.04, 0.90, and 0.97. As a result, our early ambulatory treatment regimen was associated with estimated **87.6% and 74.9% reductions in hospitalization and death** respectively, p<0.0001.

Conclusions: We conclude that early ambulatory, multidrug therapy is associated with substantial reductions in hospitalization and death compared to available rates in the community. Prompt ambulatory treatment should be offered to high-risk patients with COVID-19 instead of watchful watching and late-stage hospitalization for salvage therapies."

[911] ***Early Outpatient Treatment for COVID-19: The Evidence***
Brownstone Institute
Paul Elias Alexander
January 22, 2021
https://brownstone.org/articles/early-outpatient-treatment-for-covid-19-the-evidence/

"With highly targeted and SMDT regimens that include early application of antiviral drugs, combined with corticosteroids and anti-platelet/anti-thrombotic/anti-clotting therapeutics, the risk of hospitalization is significantly reduced by as much as by 85 to 90%, and risk of death is eliminated for high-risk patients and younger individuals presenting with severe symptoms…

Viral illnesses such as COVID-19, with complex pathophysiology, do not respond to one drug treatment but require a multi-drug approach. We have to hit the virus with multiple therapeutics. This multipronged therapeutic approach includes 1) adjuvant nutritional

supplements; 2) combination intracellular anti-infective therapy (antivirals and antibiotics); 3) inhaled/oral corticosteroids and colchicine; 4) antiplatelet agents/anticoagulants; 5) supportive care including supplemental oxygen, monitoring and telemedicine…

This brief compilation (Table 1 and Figures 1 & 2) describes a cursory summary with the direct url links of therapeutics that have been shown some degree of effectiveness if infected with COVID-19 virus in any of its variant forms including Delta and Omicron."

[912] ***Imperial County Covid story banned by Twitter and YouTube***
San Diego Reader
Eric Bartl
January 19, 2022
https://www.sandiegoreader.com/news/2022/jan/19/stringers-imperial-county-covid-banned-twitter-you/
Overcoming the COVID Darkness, by Brian Tyson and George Fareed
https://www.goodreads.com/book/show/60302902-overcoming-the-covid-darkness

"On January 7 Dr. George Fareed of Brawley and Dr. Brian Tyson of El Centro published Overcoming the Covid Darkness, their story of treating 7,000 Covid patients in the Imperial Valley since April 2020.

What makes their story unique is an early treatment protocol they've advocated since the SARS-COV-2 pandemic began and their claim to have a **100 percent survival rate** with it. Even when counting their patients who received late treatment (after five-seven days of infection,) of which three died, their protocol still has a death rate **54 times less** than the average in Imperial County [*emphasis added*], according to statistics published in The Desert Review, a weekly newspaper in the Imperial Valley."

[913] ***Coronavirus Disease 2019 (COVID-19) Treatment Guidelines***
National Institutes of Health (NIH)
Downloaded January 12, 2022
https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf

"**Evolving Knowledge on Treatment for COVID-19**

Currently, remdesivir, an antiviral agent, is the only Food and Drug Administration-approved drug for the treatment of COVID-19. An array of drugs approved for other indications and multiple investigational agents are being studied for the treatment of COVID-19 in clinical trials around the globe. These trials can be accessed at ClinicalTrials.gov. In addition, **providers can access and prescribe investigational drugs or agents that are approved or licensed for other indications through various mechanisms, including** Emergency Use Authorizations (EUAs), Emergency Investigational New Drug (EIND) applications, compassionate use or expanded access programs with drug manufacturers, and/or **off-label use** [*emphasis added*]...

Finally, it is important to stress that the rated treatment recommendations in these Guidelines should not be considered mandates. The choice of what to do or not to do for an individual patient is ultimately decided by the patient and their provider."

[914] ***Top ICU Doctor Suspended After Suing Hospital for Banning Life-Saving COVID Treatments***
The Defender
November 24, 2021
https://childrenshealthdefense.org/defender/paul-marik-lawsuit-hospital-remdesivir-ban-life-saving-drugs/
Dr. Paul E. Marik v. Sentara Healthcare, memorandum of law in support of plaintiff's motion for temporary injunction:
https://covid19criticalcare.com/wp-content/uploads/2021/11/Dr.-P.-Marik-v.-Sentara-Healthcare.pdf

> "Marik filed his lawsuit against Sentara Healthcare on Nov. 9, arguing the organization is endangering the lives of its COVID patients by preventing him from using his treatment protocol, which he says has **reduced mortality rates in the ICU** from approximately between 40% and 60% to less than 20% [*emphasis added*]…
>
> In his motion, Marik said patients are dying 'unnecessarily and unlawfully' because Sentara Healthcare is 'preventing terminally ill COVID patients from exercising their right to choose and to receive safe, potentially life-saving treatment determined to be appropriate for them by their attending physician.'
>
> In an interview with The Defender, Marik said the hospital is prohibiting the use of a COVID protocol called "Math +"…
>
> Instead, according to the lawsuit, Sentara recommends doctors use 'toxic drugs' like Remdesivir — an expensive medication associated with severe side effects — because the hospital receives a bonus each time doctors prescribe it.
>
> In a press release, Marik said: 'This case is about doctors having the ability to honor their Hippocratic Oath, to follow evidence-based medicine, and to treat our patients the best we know how. Corporations and faceless bureaucrats should not be allowed to interfere with doctor-patient decisions, especially when it can result in harm or death.'
>
> Marik, a highly published physician with 35 years of experience, said Sentara also tried to criticize his character, even though they appointed him as the director of ICU.
>
> Marik said he could no longer stand by while patients died unnecessarily without proper treatment, so he had no choice but to file a lawsuit allowing him and his colleagues to administer a combination of FDA-approved drugs and other therapies that have **saved thousands of critically ill COVID patients** in the last 18 months [*emphasis added*]."

[915] ***Physicians Declaration II***
International Alliance of Physicians and Medical Scientists (Global Covid Summit)
October 29, 2021
https://doctorsandscientistsdeclaration.org/

> For excerpts, see [377].

[916] **Video (6m): *Doctor Cites Early Treatment as Reason for Success with 6,000 Covid Patients***
Global Covid Summit
Interview with Dr. Brian Tyson of Dr. George Fareed Family Medicine
September 24, 2021
https://globalcovidsummit.org/news/doctor-cites-early-treatment-success-with-6000-covid-patients

"**Interviewer**: Dr. Tyson … you have treated how many people for COVID?

Tyson: Over 6,000… and face-to-face, not over telemedicine…

Tyson: … With early treatment between Day 1 and 7, I have not lost a single patient. Over 7 days, I've lost four.

Tyson: This is not a one-drug issue. There's no silver bullet. There is a multitude of drugs that we use, including steroids, aspirin, you name it; antivirals, antibiotics, anti-inflammatories that is in our arsenal. We put together an early-treatment protocol with Dr. Peter McCullough that was published, and it gives you a stepwise approach on how to treat these patients early. And if you follow that protocol, you're going to have a high success rate."

[917] ***Early multidrug treatment of SARS-CoV-2 infection (COVID-19) and reduced mortality among nursing home (or outpatient/ambulatory) residents***
Medical Hypotheses
Paul E. Alexander, Robin Armstrong, *et al*.
June 5, 2021
https://www.sciencedirect.com/science/article/abs/pii/S0306987721001419

"**Abstract**: … [W]e conclude that early empiric treatment for the elderly with COVID-19 in the nursing home setting (or similar congregated settings with elderly residents/patients e.g. LTF or ALF) has a reasonable probability of success and acceptable safety. This group remains our highest at-risk group and warrants acute treatment focus prior to symptoms worsening. Given the rapidity and severity of SARS-CoV-2 outbreaks in nursing homes, in-center treatment of acute COVID-19 patients is a reasonable strategy to reduce the risks of hospitalization and death. If elderly high-risk patients in such congregated nursing home type settings are allowed to worsen with no early treatment, they may be too sick and fragile to benefit from in-hospital therapeutics and are at risk for pulmonary failure, life-ending micro-thrombi of the lungs, kidneys etc…

We therefore hypothesize that early outpatient ambulatory treatment, once initiated as soon as symptoms begin in high-risk positive persons, would significantly reduce hospitalizations and prevent deaths. Specifically, the provision of early multi-drug sequenced therapy with repurposed drugs will reduce hospitalization and death in elderly patients being cared for in long-term-care facilities."

[918] ***COVID-19: Restoring Public Trust During A Global Health Crisis: An Evidence-Based Position Paper to Ensure Ethical Conduct***
GreenMedInfo
Henry L. Ealy, Michael E. McEvoy, John Nowicki, Monica Sava, and Neil M. Ruggles
March 23, 2021
https://cdn.greenmedinfo.com/sites/default/files/cdn/Position_Paper_v24_FINAL.pdf

> "During our investigation into the variety of topics this manuscript covers, a theme began to stand out as a consistent concern. Safe and effective treatments for COVID-19 are inexplicably being withheld.
>
> As you read this position paper, you will encounter many similar examples of what appears to be willful misconduct on the part of government agencies supplying inaccurate information to elected officials and the public at large.
>
> While incessant arguments persist regarding the accuracy of polymerase chain reaction (PCR) testing, asymptomatic transmission, dubious projection models, and alleged violations of federal law, the issue that is still inexplicably unresolved is the withholding of safe and effective treatments from millions of people most in need…
>
> We ask, "Is it ethical to withhold evidence-based treatments, proven to be safe and effective, from people in need?" Historically, this question has been answered with a resounding "no." Yet this is where we find ourselves again: once again, more embroiled in an age-old struggle to an ethical question we have already repeatedly answered correctly. **A common ground we must all be able to reach is that it is unethical to withhold evidence-based treatments proven to be safe and effective from people in need**.
>
> **The Intention of Our Positon Paper**
>
> The intention of our position paper is to honor our departed and everyone who has sacrificed so much so that we all might live free. In our opinion, discriminate censorship of genuine attempts to help this crisis is a major problem, as has been the repeated suppression of effective treatments for COVID-19…
>
> Detailed empirical evidence matters. This position paper is our effort to provide that detailed empirical evidence for your consideration. Difficult conversations remain, and difficult conversations require the most accurate information available."

[919] ***FMTVDM Quantitative Nuclear Imaging finds Three Treatments for SARS-CoV-2***
Biomedical Journal of Scientific & Technical Research
Richard M. Fleming and Matthew R. Fleming
February 8, 2021
https://biomedres.us/fulltexts/BJSTR.MS.ID.005443.php

> "**Introduction**: This investigation studied 10 different treatments and 52 treatment combinations to determine if there is an effective treatment regimen for SARS-CoV-2…
>
> **Methods**: 1800 people testing positive for SARS-CoV-2 from 23 sites in 7 countries were studied including outpatient and inpatient care and treatment…

Results: Of the 1800 patients seeking medical care, 847 received no outpatient treatment with 59.5 % recovering and 40.5 % requiring hospitalization. Of the 953 treated with an aminoquinoline in the outpatient setting, 16.6 % required further treatment and hospitalization… During Phase II of the study patients receiving combination treatments consisting of one of three regimens focusing on treating the immune ITR to SARS-CoV-2 responded 99.83 % of the time. These three ITR regimens consisted of

1. Tocilizumab & Interferon a-2b

2. Primaquine, Clindamycin, Tocilizumab & Interferon a-2b, and

3. Methylprednisolone.

Conclusion: The answer to the question is, Yes. The treatment of SARS-CoV-2, like HIV, requires a multi-drug treatment regimen focusing on the immune ITR to SARSCoV- 2…

These three regimens were effective 99.83 % of the time and shortened hospital stays from 40 ± 3 days to 1-2 weeks [*emphasis added*]."

[920] ***A Guide to Home-Based Treatment: Step-by-Step Doctors' Plan That Could Save Your Life***
Association of American Physicians and Surgeons
Edited by Jane Orient, Peter A. McCullough, Elizabeth Lee Vliet, and Jeremy Snavely
Updated February 1, 2021
https://faculty.utrgv.edu/eleftherios.gkioulekas/zelenko/aaps-Guide-to-Home-Based-Covid-Treatment.pdf

"**Introduction**: We provide a step-by-step guide to medically sound early treatments that have a reasonable probability of success in this emergency pandemic There are oral medications that are approved for other conditions, but not yet proven to be efficacious specifically for COVID-19 by the U.S. Food and Drug Administration. In the global pandemic emergency, large scale randomized clinical trials have not been feasible in the face of such critical illness…

There are four major pillars to infectious disease pandemic response:

1) Contagion control (stop the spread of the virus)

2) Early ambulatory, home-based treatment

3) Late-stage treatment in hospital

4) Vaccination

This guide will focus on the pillar of early, ambulatory, home-based medical treatment overseen by your physician, using a combination of available medicines, already FDA-approved for other medical conditions, and widely used in clinical medicine every day."

[921] ***Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection***
The American Journal of Medicine
Peter A. McCullough, Ronan J. Kelly, *et al*.
January 2021
https://www.sciencedirect.com/science/article/pii/S0002934320306732

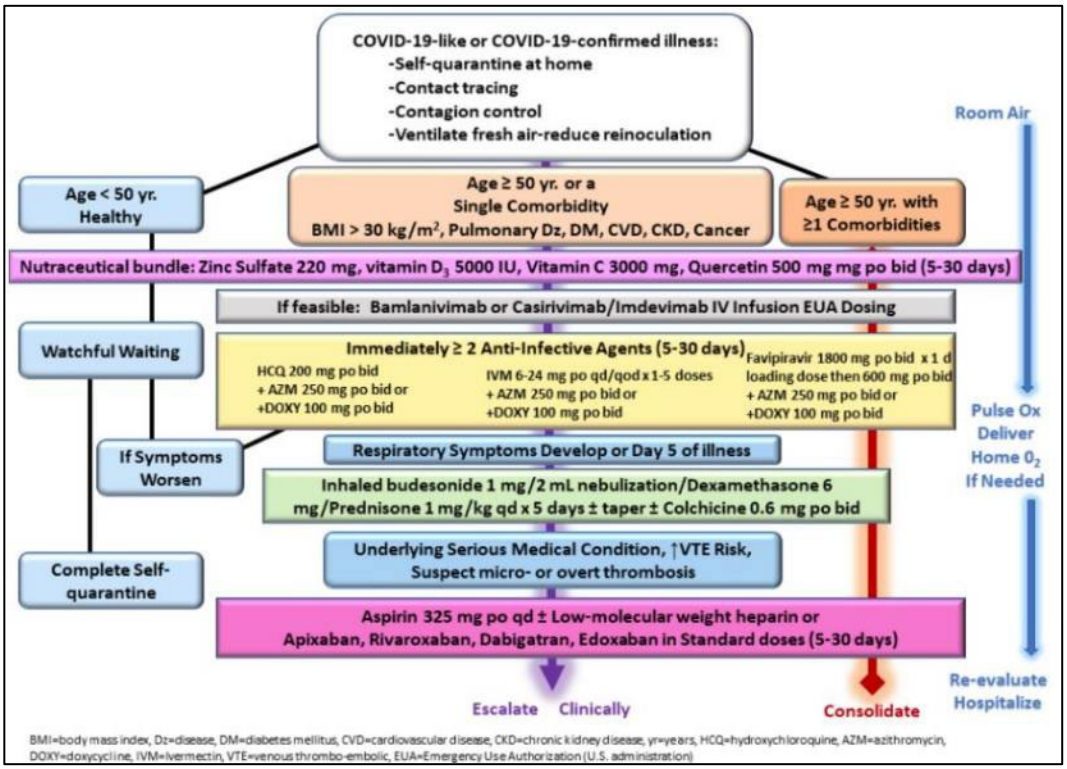
"**Clinical Significance**

- COVID-19 hospitalizations and death can be reduced with outpatient treatment.
- Principles of COVID-19 outpatient care include: 1) reduction of reinoculation, 2) combination antiviral therapy, 3) immunomodulation, 4) antiplatelet/antithrombotic therapy 5) administration of oxygen, monitoring, and telemedicine."

[922] ***Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19)***
Reviews in Cardiovascular Medicine
Peter A. McCullough, Paul E. Alexander, *et al*.
December 30, 2020
Note: A collaborative effort by 61 medical professionals and scientists, this article identifies existing treatment protocols for COVID-19, relevant studies with supporting evidence for the efficacy of protocol components (i.e., pharmaceuticals and supplements), and the therapeutic principles that should guide protocol development.
https://www.researchgate.net/publication/348357893_Multifaceted_highly_targeted_sequential_multidrug_treatment_of_early_ambulatory_high-risk_SARS-CoV-2_infection_COVID-19

"**Abstract and Figures**: … In countries where therapeutic nihilism is prevalent, patients endure escalating symptoms and without early treatment can succumb to delayed in-hospital care and death. Prompt early initiation of sequenced multidrug therapy (SMDT) is a widely and currently available solution to stem the tide of hospitalizations and death. A multipronged therapeutic approach includes 1) adjuvant nutraceuticals, 2) combination intracellular anti-infective therapy, 3) inhaled/oral corticosteroids, 4) antiplatelet agents/anticoagulants, 5) supportive care including supplemental oxygen, monitoring, and telemedicine… **An urgent immediate pivot from single drug to SMDT regimens should be employed** as a critical strategy to deal with the large numbers of acute COVID-19 patients [*emphasis added*] with the aim of reducing the intensity and duration of symptoms and avoiding hospitalization and death…

Fig. 3. Sequential multidrug treatment algorithm for ambulatory acute COVID-19 like and confirmed COVID-19 illness in patients in self-quarantine. Yr = year, BMI = body mass index, Dz = disease, DM = diabetes mellitus, CVD = cardiovascular disease, chronic kidney disease, HCQ =hydroxychloroquine, IVM = ivermectin, Mgt = management, Ox = oximetry, reproduced with permission from reference.



Introduction: Additionally, when feasible, prophylaxis could be viewed as an additional pillar since it works to reduce the spread as well as incidence of acute illness…

Our observations suggest a majority of hospitalizations could be avoided with a first treat-at-home strategy with appropriate telemedicine monitoring and access to oxygen and therapeutics…

In the absence of evidence from or a commitment to clinical trials of early therapy, other scientific information on the pathophysiology, treated natural history, and clinical judgement together must guide contemporary ambulatory management of COVID-19 (McCullough et al., 2020b). Observational studies reporting outcomes in patient populations managed consistently with empirically derived early intervention regimens currently provide an acceptable level of evidence for safety and efficacy of these widely available, inexpensive and safe alternatives to the current standard of non-intervention (Khan et al., 2020)…

Summary: … Precious time is squandered with a "wait and see" approach in which there is no anti-viral treatment as the condition worsens, possibly resulting in unnecessary hospitalization, morbidity, and death. Once infected, the only means of preventing a hospitalization in a high-risk patient is to apply treatment before arrival of symptoms that prompt paramedic calls or emergency room visits. Given the current failure of government support for randomized clinical trials evaluating widely available, generic, inexpensive therapeutics, and the lack of instructive outpatient treatment guidelines (U.S., Canada, U.K., Western EU, Australia, some South American Countries), clinicians must act according to clinical judgement and in shared decision making with fully informed patients. Early SMDT developed empirically based upon pathophysiology and evidence from randomized data and the treated natural history of COVID-19 has demonstrated safety and efficacy. In newly diagnosed, high-risk, symptomatic patients with COVID-19, SMDT has a reasonable chance

of therapeutic gain with an acceptable benefit-to-risk profile."

[923] ***Clinical and Scientific Rationale for the "MATH+" Hospital Treatment Protocol for COVID-19***
Journal of Intensive Care Medicine
Pierre Kory, G. Umberto Meduri, Jose Iglesias, Joseph Varon, and Paul E. Marik
December 15, 2020
https://journals.sagepub.com/doi/10.1177/0885066620973585

"**Abstract**: In December 2019, COVID-19, a severe respiratory illness caused by the new coronavirus SARS-CoV-2 (COVID-19) emerged in Wuhan, China. The greatest impact that COVID-19 had was on intensive care units (ICUs), given that approximately 20% of hospitalized cases developed acute respiratory failure (ARF) requiring ICU admission. Based on the assumption that COVID-19 represented a viral pneumonia and no anti-coronaviral therapy existed, nearly all national and international health care societies' recommended "supportive care only" avoiding other therapies outside of randomized controlled trials, with a specific prohibition against the use of corticosteroids in treatment. However, early studies of COVID-19-associated ARF reported inexplicably high mortality rates, with frequent prolonged durations of mechanical ventilation (MV), even from centers expert in such supportive care strategies. These reports led the authors to form a clinical expert panel called the Front-Line COVID-19 Critical Care Alliance (www.flccc.net). The panel collaboratively reviewed the emerging clinical, radiographic, and pathological reports of COVID-19 while initiating multiple discussions among a wide clinical network of front-line clinical ICU experts from initial outbreak areas in China, Italy, and New York. Based on the shared early impressions of "what was working and what wasn't working," the increasing medical journal publications and the rapidly accumulating personal clinical experiences with COVID-19 patients, a treatment protocol was created for the hospitalized patients based on the core therapies of methylprednisolone, ascorbic acid, thiamine, heparin and co-interventions (MATH+). This manuscript reviews the scientific and clinical rationale behind MATH+ based on published in-vitro, pre-clinical, and clinical data in support of each medicine, with a special emphasis of studies supporting their use in the treatment of patients with viral syndromes and COVID-19 specifically. The review concludes with a comparison of published multi-national mortality data with MATH+ center outcomes."

[924] ***COVID-19 Outpatients – Early Risk-Stratified Treatment with Zinc Plus Low Dose Hydroxychloroquine and Azithromycin: A Retrospective Case Series Study***
International Journal of Antimicrobial Agents
Roland Derwand, Martin Scholz, and Vladamir Zelenko
October 26, 2020
https://www.sciencedirect.com/science/article/pii/S0924857920304258

"**Abstract**: The aim of this study was to describe the outcomes of patients with coronavirus disease 2019 (COVID-19) in the outpatient setting after early treatment with zinc, low-dose hydroxychloroquine and azithromycin (triple therapy) dependent on risk stratification… Independent public reference data from 377 confirmed COVID-19 patients in the same community were used as untreated controls. Of 141 treated patients, **4 (2.8%) were hospitalised, which was significantly fewer (P < 0.001) compared with 58 (15.4%) of 377 untreated patients** [odds ratio (OR) = 0.16, 95% confidence interval (CI) 0.06–0.5]. One patient (0.7%) in the treatment group died versus 13 patients (3.4%) in the untreated group

[*emphasis added*] (OR = 0.2, 95% CI 0.03–1.5; P = 0.12). No cardiac side effects were observed. Risk stratification-based treatment of COVID-19 outpatients as early as possible after symptom onset using triple therapy, including the combination of zinc with low-dose hydroxychloroquine, was associated with significantly fewer hospitalisations."

[925] ***A Combination of Ivermectin and Doxycycline Possibly Blocks the Viral Entry and Modulate the Innate Immune Response in COVID-19 Patients***
Bhabha Atomic Research Centre (Mumbai)
Dharmendra Kumar Maurya
July 9, 2020
https://chemrxiv.org/engage/chemrxiv/article-details/60c74d85842e655304db34b6

"**Abstract**: … Very recently in Bangladesh, a group of doctors reported astounding success in treating patients suffering from COVID-19 with two commonly used drugs, Ivermectin and Doxycycline. In the current study we have explored the possible mechanism by which these drugs might have worked for the positive response in the COVID-19 patients… Our study shows that both Ivermectin and doxycycline have significantly bind with SARS-CoV-2 proteins but Ivermectin was better binding than doxycycline. Ivermectin showed a perfect binding site to the Spike-RBD and ACE2 interacting region indicating that it might be **interfering in the interaction of spike with ACE2 and preventing the viral entry in to the host cells**. Ivermectin also exhibited significant binding affinity with different SARS-CoV-2 structural and non-structural proteins (NSPs) which have diverse functions in virus life cycle. Significant binding of Ivermectin with RdRp indicate its role in the inhibition of the viral replication and **ultimately impeding the multiplication of the virus** [*emphasis added*]. Ivermectin also possess significant binding affinity with NSP3, NSP10, NSP15 and NSP16 which helps virus in escaping from host immune system. Molecular dynamics simulation study shows that binding of the Ivermectin with Mpro, Spike, NSP3, NSP16 and ACE2 was quiet stable. Thus, our docking and simulation studies reveal that combination of Ivermectin and doxycycline might be executing the effect by inhibition of viral entry and enhance viral load clearance by targeting various viral functional proteins…

In summary, the miraculous effect of combination of Ivermectin and doxycycline in COVID-19 patients is possibly by inhibition of spike-ACE2 interaction and inhibiting RNA dependent RNA polymerase, ADP Ribose Phosphatase, Endoribonuclease and NSP10-NSP16 complex mediated methyltransferase activities, anti-viral activity and chelation of the zinc & immunomodulatory property. Thus, the usage of Ivermectin and doxycycline combination will be an ideal choice in prevention and management of COVID-19."

[926] ***Quercetin and Vitamin C: An Experimental, Synergistic Therapy for the Prevention and Treatment of SARS-CoV-2 Related Disease (COVID-19)***
Frontiers in Immunology
Ruben Manuel Luciano Colunga Biancatelli, Max Berrill, John D. Catravas, and Paul E. Marik
June 19, 2020
https://www.frontiersin.org/articles/10.3389/fimmu.2020.01451/full

"**Introduction**: … In this review we collate the evidence of the antiviral properties of quercetin, describe its biologic action and pharmacokinetics profile, expand on our previous review of vitamin C, discuss their synergistic actions, and propose this experimental multi-drug approach for the prevention and treatment of SARS-CoV-2/COVID-19 pandemic.

Conclusion: Quercetin displays a broad range of antiviral properties which can interfere at multiple steps of pathogen virulence -virus entry, virus replication, protein assembly- and that these therapeutic effects can be augmented by the co-administration of vitamin C. Furthermore, due to their lack of severe side effects and low-costs, we strongly suggest the combined administration of these two compounds for both the prophylaxis and the early treatment of respiratory tract infections, especially including COVID-19 patients."

[927] ***Hydroxychloroquine and azithromycin plus zinc vs hydroxychloroquine and azithromycin alone: outcomes in hospitalized COVID-19 patients***
Journal of Microbiology
Philip M. Carlucci, Tania Ahuja, Christopher Petrilli, Harish Rajagopalan, Simon Jones, and Joseph Rahimian
May 8, 2020
https://www.medrxiv.org/content/10.1101/2020.05.02.20080036v1.full.pdf

"**Results**: The addition of zinc sulfate did not impact the length of hospitalization, duration of ventilation, or ICU duration. In univariate analyses, **zinc sulfate** increased the frequency of patients being discharged home, and **decreased the need for ventilation, admission to the ICU,** and **mortality or transfer to hospice** for patients who were never admitted to the ICU [*emphasis added*]. After adjusting for the time at which zinc sulfate was added to our protocol, an increased frequency of being discharged home (OR 1.53, 95% CI 1.12-2.09) reduction in mortality or transfer to hospice remained significant (OR 0.449, 95% CI 0.271-0.744)…

Conclusion: This study provides the first in vivo evidence that zinc sulfate in combination with hydroxychloroquine may play a role in therapeutic management for COVID-19."

[928] ***Triple combination of interferon beta-1b, lopinavir–ritonavir, and ribavirin in the treatment of patients admitted to hospital with COVID-19: an open-label, randomised, phase 2 trial***
The Lancet
Ivan Fan-Ngai Hung, Kwok-Cheung Lung, *et al*.
May 8, 2020
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31042-4/fulltext

"**Added value of this study**: … Treatment with the triple combination effectively suppressed viral load in all clinical specimens, including the nasopharyngeal swab, throat saliva, posterior oropharyngeal saliva, and stool in most patients 8 days from treatment commencement, which was significantly shorter than the time taken in the control group, treated with lopinavir–ritonavir alone. The triple combination also alleviated symptoms completely within 4 days—a significantly shorter time than the control. The triple combination also suppressed IL-6 levels. The clinical and virological efficacy resulted in shorter hospital stays and facilitated infection control. This treatment regimen was also shown to be safe."

Natural Supplements

Cannabidiol (CBD)

[929] ***Cannabidiol Inhibits SARS-CoV-2 Replication and Promotes the Host Innate Immune Response***
University of Chicago
Long Chi Nguyen, Dongbo Yang, *et al*.
March 10, 2021
https://www.biorxiv.org/content/10.1101/2021.03.10.432967v1.full

> "**Abstract**: The rapid spread of COVID-19 underscores the need for new treatments. Here we report that cannabidiol (CBD), a compound produced by the cannabis plant, inhibits SARS-CoV-2 infection. **CBD and its metabolite**, 7-OH-CBD, but not congeneric cannabinoids, **potently block SARS-CoV-2 replication in lung epithelial cells**. CBD acts after cellular infection, inhibiting viral gene expression and reversing many effects of SARS-CoV-2 on host gene transcription [*emphasis added*]. CBD induces interferon expression and up-regulates its antiviral signaling pathway. A cohort of human patients previously taking CBD had significantly lower SARS-CoV-2 infection incidence of up to an order of magnitude relative to matched pairs or the general population. This study highlights CBD, and its active metabolite, 7-OH-CBD, as potential preventative agents and therapeutic treatments for SARS-CoV-2 at early stages of infection."

Quercetin

Note: The citations below are presented in reverse, chronological order.

[930] ***Potential Clinical Benefits of Quercetin in the Early Stage of COVID-19: Results of a Second, Pilot, Randomized, Controlled and Open-Label Clinical Trial***
International Journal of General Medicine
Francesco Di Pierro, Somia Iqtadar, *et al*.
June 24, 2021
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8238537/

> "**Background**: … Based on the potential antiviral role of quercetin, and on its described anti-blood clotting, anti-inflammatory and antioxidant properties, we hypothesize that subjects with mild COVID-19 treated with Quercetin Phytosome® (QP), a novel bioavailable form of quercetin, may have a shorter time to virus clearance, a milder symptomatology, and higher probabilities of a benign earlier resolution of the disease…
>
> **Discussion**: … Quercetin is a natural substance that has multiple pharmacological properties, such as anti-inflammatory action, and is worldwide used as a dietary supplement. There is some recent evidence of the anti-coronavirus activities of this compound, including against SARS-CoV-2 main proteases and S-protein. Its assumed ability to inhibit coronavirus and its well-described anti-inflammatory role make quercetin a possible new candidate for outpatients' treatment of COVID-19. We have therefore tested as adjuvant supplementation an orally bioavailable form of quercetin in a pilot, randomized, controlled and open-label clinical study in

which we have enrolled 42 ambulatory COVID-19 patients. Our results demonstrated the beneficial role played by QP [*Quercetin Phytosome*] after only 1 week of add-on therapy. In particular, the use of QP at the dose of 1500 mg/day for 1 week followed using 1000 mg/day for another week (corresponding to 600 and 400 mg of quercetin per day, respectively), was demonstrated to significantly: 1) **increase the clearance of the virus**, 2) **reduce the symptoms occurrence**, 3) improve disease biomarkers [*emphasis added*]."

[931] ***Possible Therapeutic Effects of Adjuvant Quercetin Supplementation Against Early-Stage COVID-19 Infection: A Prospective, Randomized, Controlled, and Open-Label Study***
International Journal of General Medicine
Francesco Di Pierro, Giurseppe Derosa, *et al*.
June 24, 2021
https://pubmed.ncbi.nlm.nih.gov/34135619/

"**Background**: Quercetin, a well-known naturally occurring polyphenol, has recently been shown by molecular docking, in vitro and in vivo studies to be a possible anti-COVID-19 candidate. Quercetin has strong antioxidant, anti-inflammatory, immunomodulatory, and antiviral properties, and it is characterized by a very high safety profile…

Methods: In the present prospective, randomized, controlled, and open-label study, a daily dose of 1000 mg of QP was investigated for 30 days in 152 COVID-19 outpatients to disclose its adjuvant effect in treating the early symptoms and in preventing the severe outcomes of the disease.

Results: The results revealed **a reduction in frequency and length of hospitalization**, in need of non-invasive oxygen therapy, in progression to intensive care units and in **number of deaths** [*emphasis added*]. The results also confirmed the very high safety profile of quercetin and suggested possible anti-fatigue and pro-appetite properties."

Vitamin C

Note: The citations below are presented in reverse, chronological order.

[932] ***Vitamin C and COVID-19***
Frontiers in Medicine
Harri Hemila and Angelique M.E. de Man
January 18, 2021
https://www.frontiersin.org/articles/10.3389/fmed.2020.559811/full

> "In numerous animal studies, vitamin C has prevented and alleviated viral and bacterial infections. In a few dozen placebo-controlled trials with humans, vitamin C has shortened infections caused by respiratory viruses, which indicates that the vitamin can also influence viral infections in humans. In critically ill patients, plasma vitamin C levels are commonly very low. Gram doses of vitamin C are needed to increase the plasma vitamin C levels of critically ill patients to the levels of ordinary healthy people. A meta-analysis of 12 trials with 1,766 patients calculated that vitamin C reduced the length of ICU stay on average by 8%. Another meta-analysis found that vitamin C shortened the duration of mechanical ventilation in ICU patients. Two randomized placebo-controlled trials found statistically significant reduction in the mortality of sepsis patients. The effects of vitamin C on acute respiratory distress syndrome (ARDS) frequently complicating COVID-19 pneumonia should be considered. Vitamin C is a safe and inexpensive essential nutrient."

[933] ***Serum Levels of Vitamin C and Vitamin D in a Cohort of Critically Ill COVID-19 Patients of a North American Community Hospital Intensive Care Unit in May 2020: A Pilot Study***
Medicine in Drug Discovery
Cristian Arvinte, Maharaj Singh, and Paul E. Marik
September 18, 2020
https://www.sciencedirect.com/science/article/pii/S2590098620300518

> "**Objective**: The objective of this pilot study was to measure serum vitamin C and vitamin D levels in a cohort of patients with critical COVID-19 illness in our community hospital ICU…
>
> **Results**: …
>
> Serum levels of vitamin C and vitamin D were low in most of our critically ill COVID-19 ICU patients.
>
> Older age and low vitamin C level appeared co-dependent risk factors for mortality from COVID-19 in our sample…
>
> **Conclusion**: Our pilot study found low serum levels of vitamin C and vitamin D in most of our critically ill COVID-19 ICU patients. Older age and low vitamin C level appeared co-dependent risk factors for mortality. Many were also insulin-resistant or diabetic, overweight or obese, known as independent risk factors for low vitamin C and vitamin D levels, and for COVID-19.
>
> These findings suggest the need to further explore whether caring for COVID-19 patients ought to routinely include measuring and correcting serum vitamin C and vitamin D levels, and whether treating critically ill COVID-19 warrants acute parenteral vitamin C and vitamin D replacement."

[934] ***Vitamin C levels in patients with SARS-CoV-2-associated acute respiratory distress syndrome***
Critical Care – BioMed Central (BMC)
Luis Chiscano-Camon, Juan Carlos Ruiz-Rodriguez, Adolf Ruiz-Sanmartin, Oriol Roca, and Ricard Ferrer
August 26, 2020
https://ccforum.biomedcentral.com/articles/10.1186/s13054-020-03249-y

> "Vitamin C is an antioxidant with anti-inflammatory and immune-supportive properties. Its levels are decreased in patients with sepsis-related acute respiratory distress syndrome (ARDS). Moreover, a significant number of patients with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) disease developed ARDS [1]. Therefore, we hypothesized that ARDS coronavirus disease 2019 (COVID-19) patients may present vitamin C deficiency.
>
> Plasma vitamin C levels in a population of adult ICU patients COVID-19 who met ARDS criteria according to the Berlin definition were prospectively measured. The study was approved by the local Clinical Research Ethics Committee (PR (AG)270/2020)… Seventeen patients (94.4%) had **undetectable vitamin C levels** and 1 patient had low levels (2.4 mg/L) [*emphasis added*].
>
> To our knowledge, this is the first study to analyze the levels of vitamin C in patients with SARS-CoV-2-associated ARDS. Our study revealed that vitamin C levels are undetectable in more than 90% of the patients included…
>
> Moreover, vitamin C may have implications for treatment of COVID-19-associated ARDS. Indeed, one preclinical study showed that vitamin C increased resistance to infection caused by coronavirus. Moreover, other clinical studies that included surgical patients and patients with pneumonia showed encouraging results in terms of decreased incidence and severity of lung injury and mortality."

[935] ***Intravenous Ascorbic Acid for Supportive Treatment in Hospitalized COVID-19 Patients***
International Society of Orthomolecular Medicine
Paul S. Anderson
March 24, 2020
https://isom.ca/article/intravenous-ascorbic-acid-for-supportive-treatment-in-hospitalized-covid-19-patients/

> "**Abstract**: Intravenous ascorbic acid (IVAA) is a well-known intervention in medicine, which currently is rarely used in US hospitals. Due to the unusual and extreme clinical demands of hospitalized COVID-19 patients, IVAA has been implemented in Chinese hospitals, and data published by the 'Expert Group on Clinical Treatment of New Corona Virus Disease in Shanghai' (Shanghai, 2019) details the use of IVAA as safe and effective adjunctive care of hospitalized COVID-19 patients. In the IVAA treated group, there was no mortality, no reported side effects, and shorter hospital stays universally. In addition, the Shanghai Expert Group recommends IVAA use in extremely critical settings within COVID-19 patients. IVAA, as an intervention, is relatively inexpensive and simple for both pharmacy and nursing staff use…

Salient Clinical Data: … The crisis in China, and the presence of an expert in the use of IVAA in the Shanghai Expert Group, facilitated the addition of IVAA to their therapeutic interventions in the hospital treatment of patients with COVID-19. Background data and details are in the references, resources, and information below, but the points critical to use in this current crisis are:

- Chinese facility patient load: 358 total COVID-19 patients as of March 17th, 2020.
- Facility treated approximately 50 cases (of the 358) of moderate to severe COVID-19 infection with IVAA.
- The IVAA dosing was moderate and affordable (detail below) and dose determined by clinical status.
- **All patients who received IVAA improved**.
- There was no mortality in the IVAA group [*emphasis added*]
- There were no side effects reported from any patients in the IVAA group."

[936] ***Vitamin C may reduce the duration of mechanical ventilation in critically ill patients: a meta-regression analysis***
Journal of Intensive Care
Harri Hemila and Elizabeth Chalker
February 7, 2020
https://jintensivecare.biomedcentral.com/articles/10.1186/s40560-020-0432-y

"**Background**: Our recent meta-analysis indicated that vitamin C may shorten the length of ICU stay and the duration of mechanical ventilation. Here we analyze modification of the vitamin C effect on ventilation time, by the control group ventilation time (which we used as a proxy for severity of disease in the patients of each trial)…

Results: We identified nine potentially eligible trials, eight of which were included in the meta-analysis. We pooled the results of the eight trials, including 685 patients in total, and found that vitamin C shortened the length of mechanical ventilation on average by 14% ($P = 0.00001$)… Vitamin C was most beneficial for patients with the longest ventilation, corresponding to the most severely ill patients. In five trials including 471 patients requiring ventilation for over 10 h, a dosage of 1–6 g/day of vitamin C shortened ventilation time on average by 25% ($P < 0.0001$)."

[937] ***Vitamin C and Immune Function***
Nutrients - Multidisciplinary Digital Publishing Institute (MDPI)
Anitra C. Carr and Silvia Maggini
November 3, 2017
https://www.mdpi.com/2072-6643/9/11/1211/htm

"**Abstract**: … Vitamin C is an essential micronutrient for humans… It is a potent antioxidant and a cofactor for a family of biosynthetic and gene regulatory enzymes. Vitamin C contributes to immune defense by supporting various cellular functions of both the innate and adaptive immune system. Vitamin C supports epithelial barrier function against pathogens and promotes the oxidant scavenging activity of the skin, thereby potentially protecting against

environmental oxidative stress… [I]t has been shown to enhance differentiation and proliferation of B- and T-cells, likely due to its gene regulating effects. Vitamin C deficiency results in impaired immunity and higher susceptibility to infections. In turn, infections significantly impact on vitamin C levels due to enhanced inflammation and metabolic requirements. Furthermore, supplementation with vitamin C appears to be able to both prevent and treat respiratory and systemic infections. Prophylactic prevention of infection requires dietary vitamin C intakes that provide at least adequate, if not saturating plasma levels (i.e., 100–200 mg/day), which optimize cell and tissue levels. In contrast, treatment of established infections requires significantly higher (gram) doses of the vitamin to compensate for the increased inflammatory response and metabolic demand."

Vitamin D

Note: The citations below are presented in reverse, chronological order.

[938] ***Pre-infection 25-hydroxyvitamin D3 levels and association with severity of COVID-19 illness***
PLOS One (Bar-Ilan University, Israel)
Amiel A. Dror, Nicole Morozov, *et al*.
February 3, 2022
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0263069

> "**Design**: Patients admitted to GMC [*Galilee Medical Center*] with COVID-19 were categorized according to disease severity and level of 25(OH)D. An association between pre-infection 25(OH)D levels, divided between four categories (deficient, insufficient, adequate, and high-normal), and COVID-19 severity was ascertained utilizing a multivariable regression analysis…
>
> **Results**: Of 1176 patients admitted, 253 had records of a 25(OH)D level prior to COVID-19 infection. A lower vitamin D status was more common in patients with the severe or critical disease (<20 ng/mL [87.4%]) than in individuals with mild or moderate disease (<20 ng/mL [34.3%] p < 0.001). Patients with vitamin D deficiency (<20 ng/mL) were **14 times more likely to have severe or critical disease** than patients with 25(OH)D ≥40 ng/mL [*emphasis added*]."

[939] ***Vitamin D Insufficiency May Account for Almost Nine of Ten COVID-19 Deaths: Time to Act.* Comment on: "*Vitamin D Deficiency and Outcome of COVID-19 Patients*"**
Nutrients (University of Heidelberg, Germany)
Hermann Brenner and Ben Schöttker
November 20, 2021
https://www.mdpi.com/2072-6643/12/12/3642/htm

> "Evidence from observational studies is accumulating, suggesting that the majority of deaths due to SARS-CoV-2 infections are statistically attributable to vitamin D insufficiency and could potentially be prevented by vitamin D supplementation. Given the dynamics of the COVID-19 pandemic, rational vitamin D supplementation whose safety has been proven in an extensive body of research should be promoted and initiated to limit the toll of the pandemic even before the final proof of efficacy in preventing COVID-19 deaths by randomized trials…
>
> We read, with great interest, the recent article by Radujkovic et al. that reported associations between vitamin D deficiency (25(OH)D < 12 ng/mL) or insufficiency (25(OH)D < 20 ng/mL) and death in a cohort of 185 consecutive symptomatic SARS-CoV-2-positive patients admitted to the Medical University Hospital Heidelberg, who were diagnosed and treated between 18 March and 18 June 2020… these results imply that **87% of COVID-19 deaths may be statistically attributed to vitamin D insufficiency** and could potentially be avoided by eliminating vitamin D insufficiency [*emphasis added*]."

[940] ***COVID-19 Mortality Risk Correlates Inversely with Vitamin D3 Status, and a Mortality Rate Close to Zero Could Theoretically Be Achieved at 50 ng/mL 25(OH)D3: Results of a Systematic Review and Meta-Analysis***
Nutrients journal
Lorenz Borsche, Bernd Glauner, and Julian von Mendel
October 14, 2021
https://www.mdpi.com/2072-6643/13/10/3596/htm

"**Background**: Much research shows that blood calcidiol (25(OH)D3) levels **correlate strongly** with SARS-CoV-2 infection severity [*emphasis added*]. There is open discussion regarding whether low D3 is caused by the infection or if deficiency negatively affects immune defense. The aim of this study was to collect further evidence on this topic…

Results: One population study and seven clinical studies were identified, which reported D3 blood levels preinfection or on the day of hospital admission. The two independent datasets showed a negative Pearson correlation of D3 levels and mortality risk... For the combined data, median (IQR) D3 levels were 23.2 ng/mL.. Regression suggested a **theoretical point of zero mortality at approximately 50 ng/mL D3** [*emphasis added*].

Conclusions: The datasets provide strong evidence that low D3 is a predictor rather than just a side effect of the infection. Despite ongoing vaccinations, we recommend raising serum 25(OH)D levels to above 50 ng/mL to prevent or mitigate new outbreaks due to escape mutations or decreasing antibody activity."

[941] ***Seasonal UV exposure and vitamin D: Association with the dynamics of COVID-19 transmission in Europe***
FEBS Open Bio (Bar-Ilan University, Israel)
Sunanda Biswas Mukherjee, Alessandaro Gorohovski, *et al*.
October 5, 2021
https://febs.onlinelibrary.wiley.com/doi/10.1002/2211-5463.13309

"**Abstract**: Several recent studies have demonstrated that low plasma 25(OH) vitamin D levels are associated with the risk of COVID-19 infection. The primary source of vitamin D production in humans is environmental UV radiation… [W]e first performed a comprehensive meta-analysis of all related published literature based on the association of vitamin D and COVID-19, which supported the hypothesis that the low vitamin D level is a critical risk factor for COVID-19 infection. Next, to understand the potential impact of seasonal UV and temperature levels on COVID-19 cases, we analyzed meteorological data and daily COVID-19 cases per million in the populations of 26 European countries. We observed that low temperature, UV index, and cloud-free vitamin D UV dose (UVDVF) levels are negatively correlated with COVID-19 prevalence in Europe. Furthermore, a distributed lag non-linear model was used to assess the non-linear delayed effects of individual seasonal factors on COVID-19 cases. Such analysis highlighted the significantly delayed impact of UVDVF on the cumulative relative risk of COVID-19 infection. The findings of this study suggest that low UV exposure can affect the required production of vitamin D in the body, which **substantially influences the dynamics of COVID-19 transmission and severity** [*emphasis added*]."

[942] ***An observational and Mendelian randomisation study on vitamin D and COVID-19 risk in UK Biobank***
Scientific Reports
Xue Li, Jos van Geffen, *et al*.
September 14, 2021
https://www.nature.com/articles/s41598-021-97679-5

> "**Abstract**: A growing body of evidence suggests that vitamin D deficiency has been associated with an increased susceptibility to viral and bacterial respiratory infections. In this study, we aimed to examine the association between vitamin D and COVID-19 risk and outcomes. We used logistic regression to identify associations between vitamin D variables and COVID-19 (risk of infection, hospitalisation and death) in 417,342 participants from UK Biobank… **Ambient UVB was strongly and inversely associated with COVID-19 hospitalization and death overall** and consistently after stratification by BMI and ethnicity [*emphasis added*]. We also observed an interaction that suggested greater protective effect of genetically-predicted vitamin D levels when ambient UVB radiation is stronger.
>
> **Introduction**: [E]vidence suggests that COVID-19 disproportionately affects black and minority ethnic individuals, with one potential explanation being the higher prevalence of vitamin D deficiency, in addition to other risk factors. It is thus hypothesised that having adequate vitamin D levels may help reduce the risk of contracting the SARS-CoV-2 virus or reduce the risk of severe or lethal COVID-19 disease.

[943] ***Vitamin D3 and its hydroxyderivatives as promising drugs against COVID-19: a computational study***
Journal of Biomolecular Structure and Dynamics
Yuwei Song, Shariq Qayyum, *et al*.
August 20, 2021
https://www.tandfonline.com/doi/full/10.1080/07391102.2021.1964601

> "**Abstract**: … In this study, we used combined molecular docking, molecular dynamics simulations and binding free energy analyses to investigate the potentials of vitamin D3 and its hydroxyderivatives as TMPRSS2 inhibitor and to inhibit the SARS-CoV-2 receptor binding domain (RBD) binding to angiotensin-converting enzyme 2 (ACE2), as well as to unveil molecular and structural basis of 1,25(OH)2D3 capability to inhibit ACE2 and SARS-CoV-2 RBD interactions. The results show that vitamin D3 and its hydroxyderivatives are favorable to bind active site of TMPRSS2 and the binding site(s) between ACE2 and SARS-CoV2-RBD, which indicate that vitamin D3 and its biologically active hydroxyderivatives can serve as TMPRSS2 inhibitor and can inhibit ACE2 binding of SARS-CoV-2 RBD to **prevent SARS-CoV-2 entry** [*emphasis added*]."

[944] ***The sufficient vitamin D and albumin level have a protective effect on COVID-19 infection***
Archives of Microbiology
Somaieh Matin, Nasrin Fouladi, *et al*.
July 30, 2021
https://link.springer.com/article/10.1007/s00203-021-02482-5

"**Abstract**: There is limited information regarding the protective factors of SARS-CoV-2 infection. This research is focused on analyzing the role of vitamin D and albumin in the severity, progression, or possible prevention of COVID-19 infection. In this case–control study, 191 patients and 203 healthy individuals were enrolled. Blood samples were taken to test the albumin and vitamin D levels of both groups. Our results show a direct association of vitamin D deficiency with the infection of COVID-19 and severity. According to our findings, **84.4% of patients with COVID-19 in this study had vitamin D deficiency** [*emphasis added*]. Moreover, the average level of albumin was significantly decreased in those infected patients who had respiratory symptoms. In the present study, a considerable negative correlation was established between the levels of vitamin D and the severity of COVID-19 infection. This reflects on the immunomodulatory and inhibitory nature of vitamin D to the viral replication."

[945] **ADDED since 2/8/2020**
Calcifediol Treatment and COVID-19–Related Outcomes
Journal of Clinical Endocrinology & Metabolism — Hospital del Mar Medical Research Institute, Spain
Xavier Nogues, Diana Ovejero, *et al*.
June 7, 2021
https://academic.oup.com/jcem/article/106/10/e4017/6294179

"**Objective**: This work aims to elucidate the effect of 25(OH)D3 (calcifediol) treatment on COVID-19–related outcomes…

Results: ICU assistance was required by 102 (12.2%) participants. Out of 447 patients treated with calcifediol at admission, **20 (4.5%) required the ICU, compared to 82 (21%)** out of 391 nontreated (P < .001). Logistic regression of calcifediol treatment on ICU admission, adjusted by age, sex, linearized 25-hydroxyvitamin D levels at baseline, and comorbidities showed that treated patients had a reduced risk of requiring the ICU (odds ratio [OR] 0.13; 95% CI 0.07-0.23). Overall mortality was 10%. In the intention-to-treat analysis, **21 (4.7%) out of 447 patients treated with calcifediol at admission died compared to 62 patients (15.9%) out of 391 nontreated** (P = .001). Adjusted results showed a reduced mortality risk with an OR of 0.21 (95% CI, 0.10-0.43). In the second analysis, the obtained OR was 0.52 (95% CI, 0.27-0.99).

Conclusion: In patients hospitalized with COVID-19, calcifediol treatment significantly reduced ICU admission and mortality."

[946] ***Pre-infection 25-hydroxyvitamin D3 levels and association with severity of COVID-19 illness***
Galilee Medical Center (Israel)
Amiel A. Dror, Nicole g. Morozov, *et al*.
June 7, 2021
https://www.medrxiv.org/content/10.1101/2021.06.04.21258358v1.full-text

"**Objective**: Studies have demonstrated a potential link between low vitamin D levels and both an increased risk of infection with SARS-CoV-2 and poorer clinical outcomes but have not established temporality. This retrospective study examined if, and to what degree, a relationship exists between pre-infection serum vitamin D levels and disease severity and mortality of SARS-CoV-19…

Results: Of 1176 patients admitted, 253 had VitD levels prior to COVID-19 infection. Compared with mildly or moderately diseased patients, those with severe or critical COVID-19 disease were more likely to have **pre-infection vitamin D deficiency of less than 20 ng/mL** [*emphasis added*]...

Conclusions: Among hospitalized COVID-19 patients, pre-infection deficiency of vitamin D was associated with increased disease severity and mortality."

[947] **ADDED since 2/8/2022**

The Impact of Vitamin D Supplementation on Mortality Rate and Clinical Outcomes of COVID-19 Patients: A Systematic Review and Meta-Analysis

Pharmaceutical Sciences — Tabriz University of Medical Sciences, Iran
Leila Nikniaz, Mohammad Amin Akbarzadeh, Hossein Hosseinifard, and Mohammad-Salar Hosseini
March 9, 2021
https://ps.tbzmed.ac.ir/Article/ps-34133

"**Background**: Several studies have suggested the positive impact of vitamin D on patients infected with SARS-CoV-2. This systematic review aims to evaluate the effects of vitamin D supplementation on clinical outcomes and mortality rate of COVID-19 patients…

Conclusion: Prescribing vitamin D supplementation to patients with COVID-19 infection seems to decrease the mortality rate, the severity of the disease, and serum levels of the inflammatory markers."

[948] **ADDED since 2/8/2020**

High-Dose Cholecalciferol Booster Therapy is Associated with a Reduced Risk of Mortality in Patients with COVID-19: A Cross-Sectional Multi-Centre Observational Study

Nutrients
Stephanie F. Ling, Eleanor Broad, *et al*.
December 11, 2020
https://www.mdpi.com/2072-6643/12/12/3799

"**Abstract**: … A total of 986 participants with COVID-19 were studied, of whom 151 (16.0%) received cholecalciferol [*i.e., Vitamin D3*] booster therapy. In the primary cohort of 444 patients, cholecalciferol booster therapy was associated with a reduced risk of COVID-19 mortality, following adjustment for potential confounders (ORadj 0.13, 95% CI 0.05–0.35, $p < 0.001$). This finding was replicated in a validation cohort of 541 patients (ORadj 0.38, 95% CI 0.17–0.84, $p = 0.018$). In this observational study, treatment with cholecalciferol booster therapy, regardless of baseline serum 25(OH)D levels, appears to be associated with a **reduced risk of mortality** in acute in-patients admitted with COVID-19."

[949] ***Analysis of vitamin D level among asymptomatic and critically ill COVID-19 patients and its correlation with infammatory markers***
Scientific Reports – Nature (M.L.B. Medical College, India)
Anshul Jain, Rachna Chaurasia, *et al*.
November 19, 2020
https://www.nature.com/articles/s41598-020-77093-z.pdf

"Study included either asymptomatic COVID-19 patients (Group A) or severely ill patients requiring ICU admission (Group B)… The mean level of vitamin D (in ng/mL) was 27.89 ± 6.21 in Group A and 14.35 ± 5.79 in Group B, the difference was highly significant. The prevalence of vitamin D deficiency was 32.96% and 96.82% respectively in Group A and Group B…The **fatality rate was high in vitamin D deficient** (**21% vs 3.1%**) [*emphasis added*]. Vitamin D level is markedly low in severe COVID-19 patients. Infammatory response is high in vitamin D defcient COVID-19 patients. This all translates into increased mortality in vitamin D deficient COVID-19 patients. As per the flexible approach in the current COVID-19 pandemic, authors recommend mass administration of vitamin D supplements to population at risk for COVID-19…

Conclusion: Vitamin D deficiency markedly increases the chance of having severe disease after infection with SARS-Cov-2. The intensity of inflammatory response is also higher in vitamin D deficient COVID-19 patients. This all translates to increased morbidity and mortality in COVID-19 patients who are deficient in vitamin D. Keeping the current COVID-19 pandemic in view, authors recommend administration of vitamin D supplements to population at risk for COVID-19."

[950] ***Short term, high-dose vitamin D supplementation for COVID-19 disease: a randomised, placebo-controlled, study (SHADE study)***
British Medical Journal (Institute of Medical Education and Research, Chandigarh, India)
Ashu Rastogi, Anil Bhansali, *et al*.
November 12, 2020
https://pmj.bmj.com/content/postgradmedj/early/2020/11/12/postgradmedj-2020-139065.full.pdf

"**Participants**: Asymptomatic or mildly symptomatic SARS-CoV-2 RNA positive vitamin D deficient (25(OH) D<20 ng/ml) individuals.

Intervention: Participants were randomised to receive daily 60 000 IU of cholecalciferol (oral nano-liquid droplets) for 7 days with therapeutic target 25(OH) D>50 ng/ml (intervention group) or placebo (control group)…

Results: Forty SARS-CoV-2 RNA positive individuals were randomised to intervention (n=16) or control (n=24) group.… 10 (**62.5%**) participants in the intervention group and 5 (**20.8%**) participants in the control arm (p<0.018) became SARS-CoV-2 RNA negative [*emphasis added*].

Conclusion: Greater proportion of vitamin D-deficient individuals with SARS-CoV-2 infection turned SARS-CoV-2 RNA negative with a significant decrease in fibrinogen on high-dose cholecalciferol supplementation."

[951] ***Evidence Regarding Vitamin D and Risk of COVID-19 and Its Severity***
Nutrients journal
Joseph Mercola, William B. Grant. and Carol L. Wagner
October 31, 2020
https://www.mdpi.com/2072-6643/12/11/3361/htm

"**2.14. Other Nutrients That May Augment the Effectiveness of Vitamin D Supplementation**: … Although vitamin D is likely to be the most important nutrient to optimize COVID-19 prevention, other nutrients, such as magnesium, vitamin K2 and other micronutrients, are also known to impact the immune system and infection risk…

3. Conclusions: As discussed here, there is emerging evidence that higher serum 25(OH)D concentrations are associated with the reduced risk and severity of COVID-19…

The strongest evidence to date comes from **14 observational studies** that report inverse correlations between serum 25(OH)D concentrations and SARS-CoV-2 positivity and/or COVID-19 incidence, severity and/or death [*emphasis added*]."

[952] ***Vitamin D Status in Hospitalized Patients with SARS-CoV-2 Infection***
Journal of Clinical Endocrinology & Metabolism
Jose L. Hernandez, Daniel Nan, *et al*.
October 27, 2020
https://academic.oup.com/jcem/article/106/3/e1343/5934827

"**Results**: … Vitamin D deficiency was found in **82.2% of COVID-19 cases** [*emphasis added*] and 47.2% of the population-based controls… Vitamin D-deficient COVID-19 patients had a greater prevalence of hypertension and cardiovascular diseases, raised serum ferritin and troponin levels, as well as a longer length of hospital stay than those with serum 25OHD levels ≥20 ng/m."

[953] ***Vitamin D and survival in COVID-19 patients: A quasi-experimental study***
The Journal of Steroid Biochemistry and Molecular Biology
Cedric Annweiler, Berangere Hanotte, *et al.*
October 13, 2020
https://www.sciencedirect.com/science/article/pii/S096007602030296X

"**Abstract**: Vitamin D may be a central biological determinant of COVID-19 outcomes. The objective of this quasi-experimental study was to determine whether bolus vitamin D3 supplementation taken during or just before COVID-19 was effective in improving survival among frail elderly nursing-home residents with COVID-19. Sixty-six residents with COVID-19 from a French nursing-home were included in this quasi-experimental study… In conclusion, bolus vitamin D3 supplementation during or just before COVID-19 was associated in **frail elderly** with **less severe COVID-19** and **better survival rate**."

[954] **ADDED since 2/8/2022**

Impact of Serum 25(OH) Vitamin D Level on Mortality in Patients with COVID-19 in Turkey

Journal of Nutrition, Health, and Aging — Bagcilar Egitim ve Arastirma Hastanesi, Turkey
Serkan Karahan and F. Katkat
October 5, 2020
https://link.springer.com/article/10.1007/s12603-020-1479-0

"**Background**: Because of the lack of sufficient data, we aimed to investigate the role of serum 25(OH) vitamin D level on COVID severity and related mortality…

Results: Overall, 149 COVID-19 patients (females 45.6%, mean age 63.5 ± 15.3 (range 24–90 years) years) were included. Forty-seven patients (31.5%) had moderate COVID-19, whereas 102 patients (68.5%) had severe-critical COVID-19. The mean 25(OH) vitamin D level was 15.2 ± 10.3 ng/mL. Thirty-four (22.8%) and 103 (69.1%) patients had vitamin D insufficiency and deficiency, respectively. Mean serum 25(OH) vitamin D level was significantly lower in patients with severe-critical COVID-19 compared with moderate COVID-19 (10.1 ± 6.2 vs. 26.3 ± 8.4 ng/mL, respectively, p<0.001). Vitamin D insufficiency was present in **93.1%** of the patients with severe-critical COVID-19. Multivariate logistic regression analysis revealed that only lymphocyte count, white blood cell count, serum albumin and, 25(OH) vitamin D level were independent predictors of mortality."

[955] ***Effect of calcifediol treatment and best available therapy versus best available therapy on intensive care unit admission and mortality among patients hospitalized for COVID-19: A pilot randomized clinical study***

Journal of Steroid Biochemistry and Molecular Biology
Marta Entrenas Castillo, Luis Manuel Entrenas Costa, *et al*.
October 2020
https://www.sciencedirect.com/science/article/abs/pii/S0960076020302764

"**Highlights**:

- The vitamin D endocrine system have a variety of actions on cells and tissues involved in COVID-19 progression.
- Early calcifediol (25-hydroxyvitamin D) treatment to hospitalized COVID-19 patients significantly reduced intensive care unit admissions-Calcifediol seems to be able to reduce severity of the COVID-19…

Conclusion: Our pilot study demonstrated that administration of a high dose of Calcifediol or 25-hydroxyvitamin D, a main metabolite of vitamin D endocrine system, **significantly reduced the need for ICU treatment of patients** requiring hospitalization due to proven COVID-19 [*emphasis added*]."

[956] ***Serum Levels of Vitamin C and Vitamin D in a Cohort of Critically Ill COVID-19 Patients of a North American Community Hospital Intensive Care Unit in May 2020: A Pilot Study***
Medicine in Drug Discovery
Cristian Arvinte, Maharaj Singh, and Paul E. Marik
September 18, 2020
https://www.sciencedirect.com/science/article/pii/S2590098620300518

See [933]

[957] ***SARS-CoV-2 positivity rates associated with circulating 25-hydroxyvitamin D levels***
PLOS One
Harvey W. Kaufman, Justin K. Niles, Martin H. Kroll, Caixia Bi, and Michael F. Holick
September 17, 2020
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239252

"**Discussion**: … In conclusion, SARS-CoV-2 NAAT positivity is strongly and inversely associated with circulating 25(OH)D levels, a relationship that persists across latitudes, races/ethnicities, sexes, and age ranges. Our findings provide further rationale to explore the role of vitamin D supplementation in reducing the risk for SARS-CoV-2 infection and COVID-19 disease."

[958] **ADDED since 2/8/2020**
The link between vitamin D deficiency and Covid-19 in a large population
Clalit Health Services, Israel
Ariel Israel, Assi Cicurel, *et al*.
September 7, 2020
https://www.medrxiv.org/content/10.1101/2020.09.04.20188268v1.full-text

"**Methods**: We carried out a population-based study among 4.6 million members of Clalit Health Services (CHS). We collected results from vitamin D tests performed between 2010 and 2019 and used weighted linear regression to assess the relationship between prevalence of vitamin D deficiency and Covid-19 incidence in 200 localities…

Discussion: In this large population study on individuals of diverse ethnic groups, we have uncovered what appears to be a **strong and significant association** between low vitamin D levels and the risk of SARSCoV-2 infection. Individuals with low baseline vitamin D levels were significantly more prone to get infected with SARS-CoV-2…

Several potential mechanisms have been proposed to explain the observed association between vitamin D levels and the risk of Covid-19 infection. Notably, viruses could disrupt the cell junction integrity, while vitamin D may maintain cell junctions and hence decrease the risk of infection; vitamin D also enhances cellular innate immunity partly through the induction of antimicrobial peptides which can interfere with viral replication.

In our study, we observe that vitamin D supplementation, particularly in the form of drops, provides a **significant protection** against SARS-CoV-2 infection. To our knowledge, this is the first population study to identify a significant protective effect for vitamin D formulations against SARS-CoV-2."

[959] ***Vitamin D deficiency as a predictor of poor prognosis in patients with acute respiratory failure due to COVID-19***
Journal of Endocrinological Investigation
G.E. Carpagnano, V. Di Lecce, *et al*.
August 9, 2020
https://link.springer.com/article/10.1007/s40618-020-01370-x

"**Results**: … A survival analysis highlighted that, after 10 days of hospitalization, **severe vitamin D deficiency patients had a 50% mortality probability**, while those with vitamin D ≥ 10 ng/mL had a 5% mortality risk (p = 0.019) [*emphasis added*]…

Conclusions: High prevalence of hypovitaminosis D was found in COVID-19 patients with acute respiratory failure, treated in a RICU. Patients with severe vitamin D deficiency had a significantly higher mortality risk. Severe vitamin D deficiency may be a marker of poor prognosis in these patients, suggesting that adjunctive treatment might improve disease outcomes."

[960] ***Strong Correlation Between Prevalence of Severe Vitamin D Deficiency and Population Mortality Rate from COVID-19 in Europe***
Wiener klinische Wochenschrift
Isaac Z. Pugach and Sofya Pugach
July 1, 2020
https://www.medrxiv.org/content/10.1101/2020.06.24.20138644v1

"**Results**: There were 10 countries data sets that fit the criteria and were analyzed. Severe Vitamin D deficiency was defined as 25(OH)D less than 25 nmol/L (10 ng/dL). Pearson correlation analysis between death rate per million from COVID-19 and prevalence of severe Vitamin D deficiency shows a strong correlation with r = 0.76, p = 0.01, indicating significant correlation. Correlation remained significant, even after adjusting for age structure of the population. Additionally, over time, correlation strengthened, and r coefficient asymptoticaly increased."

[961] ***The role of Vitamin D in the prevention of Coronavirus Disease 2019 infection and mortality***
Aging Clinical and Experimental Research
Petre Cristian Ilie, Simina Stefanescu, and Lee Smith
May 6, 2020
https://link.springer.com/article/10.1007%2Fs40520-020-01570-8

"**Discussions**: … In conclusion, we found significant relationships between vitamin D levels and the number COVID–19 cases and **especially the mortality caused by this infection** [*emphasis added*]. The most vulnerable group of population for COVID–19 is also the one that has the most deficit in Vitamin D.

Vitamin D has already been shown to protect against acute respiratory infections and it was shown to be safe. We believe, that we can advise Vitamin D supplementation to protect against COVID–19 infection."

[962] ***Vitamin D supplementation to prevent acute respiratory tract infections: systematic review and meta-analysis of individual participant data***
British Medical Journal
Adrian R. Martineau, David A. Jolliffe, *et al*.
February 15, 2017

"**Results**: 25 eligible randomised controlled trials (total 11 321 participants, aged 0 to 95 years) were identified. IPD were obtained for 10 933 (96.6%) participants. Vitamin D supplementation reduced the risk of acute respiratory tract infection among all participants… The body of evidence contributing to these analyses was assessed as being of high quality…

Conclusions and policy implications: Our study reports a major new indication for vitamin D supplementation: the prevention of acute respiratory tract infection. We also show that people who are very deficient in vitamin D and those receiving daily or weekly supplementation without additional bolus doses experienced particular benefit. Our results add to the body of evidence supporting the introduction of public health measures such as food fortification to improve vitamin D status, particularly in settings where profound vitamin D deficiency is common."

[963] **Vitamin D and the Immune System**
Journal of Investigative Medicine
Cynthia Aranow
March 2, 2011
https://jim.bmj.com/content/59/6/881

"**Abstract**: … Vitamin D can modulate the innate and adaptive immune responses. Deficiency in vitamin D is associated with increased autoimmunity and an increased susceptibility to infection. …

The immune system defends the body from foreign, invading organisms, promoting protective immunity while maintaining tolerance to self. The implications of vitamin D deficiency on the immune system have become clearer in recent years and in the context of vitamin D deficiency, there appears to be an increased susceptibility to infection and a diathesis, in a genetically susceptible host to autoimmunity."

Zinc

Note: The citations below are presented in reverse, chronological order.

[964] **ADDED since 2/8/2022**
Twice-Daily Oral Zinc in the Treatment of Patients With Coronavirus Disease 2019: A Randomized Double-Blind Controlled Trial
Clinical Infectious Diseases — University of Monastir, Tunisia
Saoussen Ben Abdallah, Yosra Mhalla, *et al*.
November 4, 2022
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac807/6795268

"**Background**: Zinc supplementation has been considered a potential therapy for coronavirus disease 2019 (COVID-19). We aimed to examine zinc efficacy in adult patients with COVID-19 infection.

Methods: We conducted a prospective, randomized, double-blind, placebo-controlled multicenter trial…

Results: 190 patients (40.4%) were ambulatory and 280 patients (59.6%) were hospitalized. **Mortality at 30 days** was 6.5% in the zinc group and 9.2% in the placebo group (OR: .68; 95% CI .34–1.35); **ICU admission rates** were, respectively, 5.2% and 11.3% (OR: .43; 95% CI .21–.87). Combined outcome was lower in the zinc group versus the placebo group (OR: .58; 95% CI .33–.99). Consistent results were observed in prespecified subgroups of patients aged <65 years, those with comorbidity, and those who needed oxygen therapy at baseline. Length of hospital stay was shorter in the zinc group versus the placebo group (difference: 3.5 days; 95% CI 2.76–4.23) in the inpatient group; duration of COVID-19 symptoms decreased with zinc treatment versus placebo in outpatients (difference: 1.9 days; 95% CI .62–2.6). No severe adverse events were observed during the study.

Conclusions: Our results showed that, in COVID-19 patients, oral zinc can decrease 30-day death, ICU admission rate and can shorten symptom duration."

[965] ***Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection***
The American Journal of Medicine
Peter A. McCullough, Ronan J. Kelly, *et al*.
January 2021
https://www.sciencedirect.com/science/article/pii/S0002934320306732

"**Combination Antiviral Therapy**: … Zinc is a known inhibitor of coronavirus replication. Clinical trials of zinc lozenges in the common cold have demonstrated modest reductions in the duration and or severity of symptoms. By extension, this readily available nontoxic therapy could be deployed at the first signs of COVID-19. Zinc lozenges can be administered 5 times a day for up to 5 days and extended if needed if symptoms persist. The amount of elemental zinc lozenges is <25% of that in a single 220-mg zinc sulfate daily tablet. This dose of zinc sulfate has been effectively used in combination with antimalarials in early treatment of high-risk outpatients with COVID-19."

[966] ***Zinc treatment of outpatient COVID-19: A retrospective review of 28 consecutive patients***
Journal of Medical Virology
Eric Finzi and Allan Harrington
January 21, 2021
https://onlinelibrary.wiley.com/doi/10.1002/jmv.26812

> "All 28 patients were improved after 7 days of zinc… No patients were hospitalized after zinc treatment…
>
> In mild cases of COVID-19 about 80% of patients begin improving after Day 10; 20% worsen the second week. **Zinc treated patients began improvement after 1.6 days on average** [*emphasis added*]."

[967] ***Low zinc levels at clinical admission associates with poor outcomes in COVID-19***
Universitat Pompeu Fabra (Spain)
Marina Vogel-González, Marc Talló-Parra, *et al*.
October 11, 2020
https://www.medrxiv.org/content/10.1101/2020.10.07.20208645v1.full-text

> "**Background**: Biomarkers to predict Coronavirus disease-19 (COVID-19) outcome early at infection are urgently needed to improve prognosis and treatment. Zinc balances immune responses and also has a proven direct antiviral action against some viruses. Importantly, zinc deficiency (ZD) is a common condition in elderly and individuals with chronic diseases, two groups with more severe COVID-19 outcomes. We hypothesize that serum zinc content (SZC) influences COVID-19 disease progression and thus might represent a useful biomarker…
>
> **Findings**: Our study demonstrates a correlation between serum zinc levels and COVID-19 outcome. Serum zinc levels lower than 50 µg/dl at admission correlated with worse clinical presentation, longer time to reach stability and higher mortality. Our in vitro results indicate that **low zinc levels favor viral expansion** in SARS-CoV2 infected cells [*emphasis added*]."

[968] **ADDED since 2/8/2022**
Case Report: ***Treatment of SARS-CoV-2 with high dose oral zinc salts: A report on four patients***
International Journal of Infectious Diseases
Eric Finzi
October 2020
https://www.sciencedirect.com/science/article/pii/S1201971220304410

> "**Abstract**: … We report here on four consecutive outpatients with clinical characteristics (CDC case definition) of and/or laboratory-confirmed COVID-19 who were treated with high dose zinc salt oral lozenges. All four patients experienced significant improvement in objective and symptomatic disease measures after one day of high dose therapy suggesting that zinc therapy was playing a role in clinical recovery."

[969] ***Lower zinc levels in the blood are associated with an increased risk of death in patients with COVID-19***
Medical Xpress
European Society of Clinical Microbiology and Infectious Diseases
September 23, 2020
https://medicalxpress.com/news/2020-09-zinc-blood-death-patients-covid-.html

"New research presented at this week's ESCMID Conference on Coronavirus Disease (ECCVID, held online from 23-25 September) shows that having a lower level of zinc in the blood is associated with a poorer outcome in patients with COVID-19...

Mean baseline zinc levels among the 249 patients were 61 mcg/dl. Among those who died, the zinc levels at baseline were significantly lower at 43mcg/dl vs 63.1mcg/dl in survivors…

After adjusting by age, sex, severity and receiving hydroxychloroquine, statistical analysis showed **each unit increase of plasma zinc** at admission to hospital **was associated with a 7% reduced risk of in-hospital mortality**. Having a plasma zinc level lower than 50mcg/dl at admission was associated with a **2.3 times increased risk of in-hospital death** compared with those patients with a plasma zinc level of 50mcg/dl or higher [*emphasis added*]."

[970] ***COVID-19: Poor outcomes in patients with zinc deficiency***
International Journal of Infectious Diseases
Dinesh Jothimani, Ezhilarasan Kailasam, *et al*.
September 10, 2020
https://www.ijidonline.com/article/S1201-9712(20)30730-X/fulltext

"**Highlights**:

- Patients with coronavirus disease 2019 (COVID-19) had significantly low zinc levels in comparison to healthy controls.
- Zinc deficient patients developed more complications (**70.4% vs 30.0%**, p = 0.009) [*emphasis added*].
- Zinc deficient COVID-19 patients had a prolonged hospital stay (7.9 vs 5.7 days, p = 0.048).
- In vitro studies have shown that reduced zinc levels favour the interaction of angiotensin-converting enzyme 2 (ACE2) with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein and likewise that increased zinc levels inhibit ACE2 expression resulting in reduced viral interaction.

Results: … Amongst the COVID-19 patients, 27 (57.4%) were found to be zinc deficient. These patients were found to have higher rates of complications (p = 0.009), acute respiratory distress syndrome (18.5% vs 0%, p = 0.06), corticosteroid therapy (p = 0.02), prolonged hospital stay (p = 0.05), and increased mortality (18.5% vs 0%, p = 0.06)."

[971] ***The Potential Impact of Zinc Supplementation on COVID-19 Pathogenesis***
Frontiers in Immunology
Inga Wessels, Benjamin Rolles, and Lothar Rink
July 10, 2020
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7365891/

> "**Conclusion**: In this perspective, we reviewed the most important literature on the role of zinc homeostasis during viral infections, focusing on the potential benefits of zinc supplementation to prevent and treat SARS-CoV2 infections. Although data specifically on SARS-CoV2 are unfortunately still pending and randomized controlled studies have not been conducted, the enumerated evidence from the literature strongly suggests great benefits of zinc supplementation. **Zinc supplementation** improves the mucociliary clearance, **strengthens the integrity of the epithelium**, **decreases viral replication**, **preserves antiviral immunity**, attenuates the risk of hyper-inflammation, supports anti-oxidative effects and thus **reduces lung damage** and minimized secondary infections [*emphasis added*]. Especially older subjects, patients with chronic diseases and most of the remaining COVID-19 risk groups would most likely benefit. Although studies are needed testing the effect of zinc as therapeutic option for established disease, preventive supplementation of subjects from risk groups should begin now, as zinc is a cost-efficient, globally available and simple to use option with little to no side effects."

[972] ***Zinc deficiency enhanced inflammatory response by increasing immune cell activation and inducing IL6 promoter demethylation***
Molecular Nutrition & Food Research
Carment P. Wong, Nicole A. Rinaldi, and Emily Ho
February 5, 2015
https://onlinelibrary.wiley.com/doi/10.1002/mnfr.201400761

> "**Scope**: Zinc deficiency results in immune dysfunction and promotes systemic inflammation. The objective of this study was to examine the effects of zinc deficiency on cellular immune activation and epigenetic mechanisms that promote inflammation. This work is potentially relevant to the aging population given that age-related immune defects, including chronic inflammation, coincide with declining zinc status…
>
> **Conclusion**: Zinc deficiency induced inflammatory response in part by eliciting aberrant immune cell activation and altered promoter methylation. Our results suggested potential interactions between zinc status, epigenetics, and immune function, and how their dysregulation could contribute to chronic inflammation."

[973] **ADDED since 2/8/2020**
Discovery of Human Zinc Deficiency: Its Impact on Human Health and Disease
Advances in Nutrition
Ananda S. Prasad
March 2013
https://www.sciencedirect.com/science/article/pii/S2161831322011024

"**Abstract**: The essentiality of zinc in humans was established in 1963. During the past 50 y, tremendous advances in both clinical and basic sciences of zinc metabolism in humans have been observed... Zinc is a second messenger of immune cells, and intracellular free zinc in these cells participate in signaling events. Zinc… is very effective in decreasing the incidence of infection in the elderly. Zinc not only modulates cell-mediated immunity but is also an antioxidant and anti-inflammatory agent."

[974] ***Zn^{2+} Inhibits Coronavirus and Arterivirus RNA Polymerase Activity In Vitro and Zinc Ionophores Block the Replication of These Viruses in Cell Culture***
PLOS Pathogens
Aartjan J. W. te Velthuis, Sjoerd H. E. van den Worm, *et al*.
November 4, 2010
https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1001176

"**Abstract**: Increasing the intracellular Zn^{2+} concentration with zinc-ionophores like pyrithione (PT) can efficiently impair the replication of a variety of RNA viruses, including poliovirus and influenza virus. For some viruses this effect has been attributed to interference with viral polyprotein processing. In this study we demonstrate that the combination of Zn^{2+} and PT at low concentrations (2 μM Zn^{2+} and 2 μM PT) inhibits the replication of SARS-coronavirus (SARS-CoV) and equine arteritis virus (EAV) in cell culture."

Other Natural Substances

[975] **ADDED since 2/8/2020**
Scientists find antibodies that neutralize all known strains of Covid
Free Press International News Service
September 11, 2022
https://freepressers.com/articles/scientists-find-antibodies-that-neutralize-all-known-strains-of-covid
Study: ***Conformational flexibility in neutralization of SARS-CoV-2 by naturally elicited anti-SARS-CoV-2 antibodies***
Nature Communications Biology — Tel Aviv University
Ruofan Li, Michael Mor, *et al*.
August 5, 2022
https://www.nature.com/articles/s42003-022-03739-5

"Researchers at Tel Aviv University reported that they found **two antibodies that neutralize all known strains of Covid-19 with up to 95% efficiency**…

'In our view, targeted treatment with antibodies and their delivery to the body in high concentrations can serve as an effective substitute for repeated boosters, especially for at-risk populations and those with weakened immune systems. COVID-19 infection can cause

serious illness, and we know that providing antibodies in the first days following infection can stop the spread of the virus.'

'It is, therefore, possible that by using effective antibody treatment, we will not have to provide booster doses to the entire population every time there is a new variant,' [*Dr. Natalia*] Freund concluded."

[976] ***Lysine Therapy for SARS-CoV-2***
Bio-Virus Research
Christopher Kagan, Alexander Chaihorsky, Rony Tal, and Bo Karlicki
September 2020
https://www.researchgate.net/publication/344210822_Lysine_Therapy_for_SARS-CoV-2

"[O]ur group, Bio-Virus Research, has been working on both universal vaccines and universal therapeutic approaches for decades. In this letter we report our current results using L- lysine therapeutically against SARS-CoV-2…

Approximately 80% of acute stage Covid-19 sufferers given lysine displayed a **minimum 70% reduction in symptoms in the first 48 hours** (not including long term symptomatic subjects) [*emphasis added*]. Excluding long term subjects, treatment times vary from 2 days to 3.5 weeks, with many variables at play. Patients who started lysine in the hospital were discharged an average of 3 days after starting treatment…

One of the most important observations in relation to lysine was the incredibly short time to eliminate/reduce fever presumably due to extinguishing the associated cytokine storm. Cytokine storm appears to be extinguished in hours, based on the 5 inpatients who appeared to be in severe crisis when lysine was administered who showed very rapid reduction in symptoms and stabilization… These clinical results suggest that lysine appears highly suppressive of viral replication, and if these results are confirmed by further studies, lysine should significantly flatten the curve, reduce mortality and hospital bed utilization while we await a curative vaccine or vaccines, ideally one with universal application across the entire Coronavirus group."

[977] ***Mitigation of the replication of SARS-CoV-2 by nitric oxide in vitro***
Redox Biology
Dario Akaberi, Janina Krambrich, *et al*.
September 21, 2020
https://www.sciencedirect.com/science/article/pii/S2213231720309393

"**Conclusions**: In this study, we demonstrated that NO can inhibit the replication of SARS-CoV-2 in Vero E6 and we identified the SARS-CoV-2 main protease as a target for NO. There is a great need for effective antivirals against SARS-CoV-2 to be used in the on-going COVID-19 pandemic. Based on this study and previous studies on SARS-CoV in vitro, and in a small clinical trial, we conclude that NO may be applied for clinical use in the treatment of COVID-19 and other human coronavirus infections."

Conventional Medicine

Bromhexine

Note: The citations below are presented in reverse, chronological order.

[978] **ADDED since 2/8/2022**
Bromhexine Hydrochloride Prophylaxis of COVID-19 for Medical Personnel: A Randomized Open-Label Study
Interdisciplinary Perspectives on Infectious Diseases — Almazov National Medical Research Centre, Russia
Tamara A. Lyubimtseva, Aleksandr D. Vakhrushev, *et al*.
January 29, 2022
https://www.hindawi.com/journals/ipid/2022/4693121/

"**Introduction**: … We aimed to assess the preventive potential of regular bromhexine hydrochloride intake for reduction of the risk of COVID-19 in medical staff actively involved in the evaluation and treatment of patients with confirmed or suspected SARS-CoV-2 infection. The study was conducted in the period before any vaccine against COVID-19 became available…

Discussion: Although generally underpowered, the present study has several important findings. The primary combined endpoint, the rate of positive nasopharyngeal swab PCR tests for SARS-CoV-2 or symptomatic COVID-19, was similar in both groups. However, there was a trend towards a lower rate of the positive swab PCR test in the bromhexine hydrochloride treatment group. Importantly, the **rate of clinically significant SARS-CoV-2 infection was statistically lower** in the treatment group (0/25 participants) compared with the control group (5/25 participants)."

[979] **ADDED since 2/8/2022**
Bromhexine, for Post Exposure COVID-19 Prophylaxis: A Randomized, Double-Blind, Placebo Control Trial
Preprints with The Lancet — Shahid Beheshti University of Medical Sciences, Iran
Ramin Tolouian, Omid Moradi, *et al*.
December 20, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3989849

"**Methods**: A multi-center randomized; double-blind, placebo-controlled clinical trial was conducted. The 372 adults (≥18 years) who had close contact within 4 days with a household member with confirmed COVID-19 were randomly assigned to receive bromhexine (n=187) or placebo (n=185) three times a day for two weeks…

Findings: The incidence of symptomatic COVID-19 was **significantly lower** in individuals who received bromhexine than in those who received the placebo (16 [8.6%] vs 34 [18.4%], relative risk=0.47, p=0.005). PCR-confirmation was reported in 13 (7.0%) and 26 (14.1%) of the individuals in the bromhexine and placebo groups, respectively (p= 0.025), with a relative risk reduction of 50%."

[980] **ADDED since 2/8/2022**

Bromhexine Hydrochloride Tablets for the Treatment of Moderate COVID-19: An Open-Label Randomized Controlled Pilot Study

Clinical and Translational Science — Wenzhou Medical University, China
September 3, 2020
https://ascpt.onlinelibrary.wiley.com/doi/full/10.1111/cts.12881

"**Discussion**: To the best of our knowledge, this pilot study is the first to assess the efficacy and safety of BRH for the treatment of patients with COVID-19. The primary end points and the secondary outcomes did not reach significant difference between the two groups. However, the **proportion of remarkable/complete improvement in patients who had chest CTs** and the **discharge rate within 20 days in the BRH group were 2-fold higher than the control group** in value. In addition, the rate of hepatic injury in the BRH group was twofold lower than the control group. These results may suggest that BRH tablets at a dose of 32 mg t.i.d. help to alleviate hepatic or lung injury induced by SARS-CoV-2. No Bromhexine-related adverse drug reactions were found in this study, which indicated 32 mg t.i.d. oral BRH could be safe. A further definitive large-scale clinical trial is feasible and necessary to evaluate its effects and safety."

[981] **ADDED since 2/8/2022**

Effect of bromhexine on clinical outcomes and mortality in COVID-19 patients: A randomized clinical trial

BioImpacts — Tabriz University, Iran
Khalil Ansarin, Ramin Tolouian, *et al*.
July 19, 2020
https://bi.tbzmed.ac.ir/Article/bi-23240

"**Introduction**: Bromhexine is a potential therapeutic option in COVID-19, but no data from a randomized clinical trial has been available. The present study aimed to evaluate the efficacy of bromhexine in intensive care unit (ICU) admission, mechanical ventilation, and mortality in patients with COVID-19…

Results: A total of 78 patients with similar demographic and disease characteristics were enrolled. There was a significant reduction in **ICU admissions** (2 out of 39 vs. 11 out of 39, P = 0.006), **intubation** (1 out of 39 vs. 9 out of 39, P = 0.007) and **death** (0 vs. 5, P = 0.027) in the bromhexine treated group compared to the standard group. No patients were withdrawn from the study because of adverse effects.

Conclusion: The early administration of oral bromhexine reduces the ICU transfer, intubation, and the mortality rate in patients with COVID-19. This affordable medication can easily be administered everywhere with a huge positive impact(s) on public health and the world economy. Altogether, the verification of our results on a larger scale and different medical centers is strongly recommended."

[982] **ADDED since 2/8/2022**
Results of an Open Prospective Controlled Comparative Study on the Treatment of Novel Coronavirus Infection (COVID-19): Bromhexine & Spironolactone for the Treatment of Coronavirus Infection Requiring Hospitalization
Cardiology — Lomonosov Moscow State University, Russia
V.Y. Mareev, Y.A. Orlova, *et al*.
May 11, 2020
https://lib.ossn.ru/jour/article/view/1440/861

"**Introduction**: The aim of this study was to assess the efficacy and safety of a combination of bromhexine at a dose of 8 mg 4 times a day and spironolactone 50 mg per day in patients with mild and moderate COVID 19…

Results: … Analysis for the group as a whole revealed a statistically significant **reduction in hospitalization time** from **10.4 to 9.0 days** (by 1.5 days, p=0.033) and **fever time** from **6.5 to 3.9 days** (by 2.5 days, p<0.001)… Virus elimination by the 10th day was recorded in all patients in the bromhexine/spironolactone group; the control group viremia continued in 23.3% (p=0.077). The number of patients who had a positive PCR to the SARS-CoV-2 virus on the 10th day of hospitalization or longer (≥10 days) hospitalization in the control group was 20/21 (95.2%), and in the group with bromhexine/spironolactone –14/24 (58.3%), p=0.012…

Conclusion: The combination of bromhexine with spironolactone appeared effective in treating a new coronavirus infection by achieving a faster normalization of the clinical condition, lowering the temperature one and a half times faster, and reducing explanatory combine endpoint the viral load or long duration of hospitalization (≥10 days)."

Budesonide

[983] ***Budesonide Works***
Presents "links to peer-reviewed studies, articles in medical journals, or news articles regarding the efficacy of budesonide."
https://budesonideworks.com/validation-2/

Note: The citations below are presented in reverse, chronological order.

[984] ***Antiviral Effect of Budesonide against SARS-CoV-2***
Multidisciplinary Digital Publishing Institute (MDPI)
Natalie Heinen, Toni Luise Meister, Mara Klöhn, Eike Steinmann, Daniel Todt, and Stephanie Pfaender
July 20, 2021
https://www.mdpi.com/1999-4915/13/7/1411/htm

"**Discussion**: Recent observations by Ramakrishnan et al. suggest that the inhaled corticosteroid budesonide reduces clinical recovery times and prevents progression and clinical deterioration during mild COVID-19 infection… [W]e observed significant reduction of viral titers for all viral variants in vitro when cells were treated with 25 µM budesonide. These results are in accordance with previous studies that demonstrated the suppression of SARS-

CoV-2 and MERS-CoV RNA copy number by targeting the viral replication–transcription complex."

[985] ***ProLung™-budesonide Inhibits SARS-CoV-2 Replication and Reduces Lung Inflammation***
bioRxiv
Kameswari S. Konduri, Ram Pattisapu, *et al*.
May 5, 2021
https://www.biorxiv.org/content/10.1101/2021.05.05.442779v1.full

"**Conclusions**: ProLung™-budesonide significantly inhibited viral replication in SARS-CoV-2 infected cells. It localized into type II pneumocytes, decreased lung inflammation, AHR and EPO activity with Mch challenge. This novel drug formulation may offer a potential inhalational treatment for COVID-19."

[986] ***Inhaled budesonide for COVID-19 in people at higher risk of adverse outcomes in the community: interim analyses from the PRINCIPLE trial***
PRINCIPLE Collaborative Group
Ly-Mee Yu, Mona Fafadhel, *et al*.
April 12, 2021
https://www.medrxiv.org/content/10.1101/2021.04.10.21254672v1.full-text

"**Methods**: We performed a multicenter, open-label, multi-arm, adaptive platform randomized controlled trial involving people aged ≥65 years, or ≥50 years with comorbidities, and unwell ≤ 14 days with suspected COVID-19 in the community (PRINCIPLE)…

Results: … Time to first self-reported recovery was shorter in the budesonide group compared to usual care (hazard ratio 1.208 [95% BCI 1.076 – 1.356], probability of superiority 0.999, estimated benefit [95% BCI] of 3.011 [1.134 – 5.41] days). Among those in the interim budesonide primary analysis who had the opportunity to contribute data for 28 days follow up, there were 59/692 (8.5%) COVID-19 related hospitalizations/deaths in the budesonide group vs 100/968 (10.3%) in the usual care group (estimated percentage benefit, 2.1% [95% BCI −0.7% – 4.8%], probability of superiority 0.928)."

[987] ***Inhaled budesonide in the treatment of early COVID-19 (STOIC): a phase 2, open-label, randomised controlled trial***
The Lancet
Sanjay Ramakrishnan, Dan V. Nicolau Jr., *et al*.
April 9, 2021
https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00160-0/fulltext

"**Interpretation**: Early administration of inhaled budesonide reduced the likelihood of needing urgent medical care and reduced time to recovery after early COVID-19 [*emphasis added*]…

Discussion: We have shown that the inhaled glucocorticoid budesonide, given for a short duration, might be an effective treatment of early COVID-19 in adults. This effect, with a relative reduction of 91% of clinical deterioration is equivalent to the efficacy seen after the use of COVID-19 vaccines and greater than that reported in any treatments used in hospitalised patients and patients with severe COVID-19."

Fluvoxamine

Note: The citations below are presented in reverse, chronological order.

[988] ***Effect of early treatment with fluvoxamine on risk of emergency care and hospitalisation among patients with COVID-19: the TOGETHER randomised, platform clinical trial***
The Lancet Global Health
Gilmar Reis, Eduardo Augusto dos Santos Moreira-Silva, *et al*.
October 27, 2021
https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00448-4/fulltext

> "**Findings**: … 741 patients were allocated to fluvoxamine and 756 to placebo…
>
> **Interpretation**: **Treatment with fluvoxamine** (100 mg twice daily for 10 days) among high-risk outpatients with early diagnosed COVID-19 **reduced the need for hospitalization** [*emphasis added*] defined as retention in a COVID-19 emergency setting or transfer to a tertiary hospital…
>
> **Discussion**: This is, to the best of our knowledge, the first large, randomised controlled trial to test the efficacy of fluvoxamine for acute treatment of COVID-19. We found a clinically important absolute risk reduction of 5.0%, and 32% RR [*relative risk*] reduction, on the primary outcome of hospitalisation defined as either retention in a COVID-19 emergency setting or transfer to tertiary hospital due to COVID-19, consequent on the administration of fluvoxamine for 10 days."

[989] **ADDED since 2/8/2020**
Prospective Cohort of Fluvoxamine for Early Treatment of Coronavirus Disease 19
Open Forum Infectious Diseases — Golden Gate Fields Medical Clinic, California
David Seftel and David R. Boulware
February 1, 2021
https://academic.oup.com/ofid/article/8/2/ofab050/6124100

> "**Abstract**: We report a real-world experience using fluvoxamine for coronavirus disease 19 (COVID-19) in a prospective cohort in the setting of a mass outbreak. Overall, 65 persons opted to receive fluvoxamine (50 mg twice daily) and 48 declined. Incidence of hospitalization was **0%** (0 of 65) with fluvoxamine and **12.5%** (6 of 48) with observation alone. At 14 days, residual symptoms persisted in 0% (0 of 65) with fluvoxamine and 60% (29 of 48) with observation."

[990] ***Fluvoxamine vs Placebo and Clinical Deterioration in Outpatients With Symptomatic COVID-19: A Randomized Clinical Trial***
Journal of the American Medical Association (JAMA)
Eric J. Lenze, Caline Mattar, *et al*.
November 12, 2020
https://jamanetwork.com/journals/jama/fullarticle/2773108

> "**Findings**: In this randomized trial that included 152 adult outpatients with confirmed COVID-19 and symptom onset within 7 days, clinical deterioration occurred in 0 patients treated with fluvoxamine vs 6 (8.3%) patients treated with placebo over 15 days, **a difference that was statistically significant** [*emphasis added*]."

Hydroxychloroquine and Azithromycin

[991] ***HCQ for COVID-19***
https://c19hcq.com/

> "Database of all HCQ COVID-19 studies. 363 studies, 265 peer reviewed, 297 comparing treatment and control groups. HCQ is not effective when used very late with high dosages over a long period (RECOVERY/SOLIDARITY), effectiveness improves with earlier usage and improved dosing. Early treatment consistently shows positive effects."

[992] ***HCQ for COVID-19: real-time meta analysis of 297 studies***
https://hcqmeta.com/
Introduction: "We analyze all significant studies concerning the use of HCQ (or CQ) for COVID-19. Search methods, inclusion criteria, effect extraction criteria (more serious outcomes have priority), all individual study data, PRISMA answers, and statistical methods are detailed in Appendix 1. We present random-effects meta-analysis results for all studies, for studies within each treatment stage, for mortality results only, after exclusion of studies with critical bias, and for Randomized Controlled Trials (RCTs) only."

- "97% of the 33 early treatment studies report a positive effect (14 statistically significant in isolation).
- Meta analysis using the most serious outcome reported shows 64% [54-72%] improvement for the 33 early treatment studies…
- 83% of Randomized Controlled Trials (RCTs) for early, PrEP, or PEP treatment report positive effects, the probability of this happening for an ineffective treatment is 0.0038."

[993] ***Open letter from medical doctors and health professionals to all Belgian authorities and all Belgian media***
Doctors for Open Debate
September 5, 2020
https://docs4opendebate.be/en/open-letter/
Signatories: https://docs4opendebate.be/en/signatories/
Note: As of May 2, 2021, the Signatories page cites a total of 760 medical doctors and 2,887 medically trained health professionals.

> "[T]here is an affordable, safe and efficient therapy available for those who do show severe symptoms of disease in the form of HCQ (hydroxychloroquine), zinc and azithromycin. Rapidly applied, this therapy leads to recovery and often prevents hospitalisation. Hardly anyone has to die now.
>
> **This effective therapy has been confirmed by the clinical experience of colleagues in the field with impressive results**. This contrasts sharply with the theoretical criticism (insufficient substantiation by double-blind studies) which in some countries (e.g. the Netherlands) has even led to a ban on this therapy. **A meta-analysis in The Lancet, which could not demonstrate an effect of HCQ, was withdrawn**. The primary data sources used proved to be unreliable and 2 out of 3 authors were in conflict of interest [*emphasis added*]."

Note: The citations below are presented in reverse, chronological order.

[994] ***Observational Study on 255 Mechanically Ventilated Covid Patients at the Beginning of the USA Pandemic***
Smith Center for Infectious Diseases and Urban Health
Leon G. Smith, Nicolas Mendoza, David Dobesh, and Stephen M. Smith
May 31, 2021
https://www.medrxiv.org/content/10.1101/2021.05.28.21258012v1.full-text

"**Introduction**: This observational study looked at 255 COVID19 patients who required invasive mechanical ventilation (IMV) during the first two months of the US pandemic…

Results: By discharge or Day 90, 78.2% of the cohort expired. The most common pre-existing conditions were hypertension, (63.5%), diabetes (59.2%) and obesity (50.4%)… Causal modeling establishes that weight-adjusted **HCQ and AZM therapy improves survival by over 100%** [*emphasis added*]."

[995] ***The Key to Defeating COVID-19 Already Exists. We Need to Start Using It***
Newsweek
Harvey Risch, Professor of Epidemiology, Yale School of Public Health
July 23, 2020
https://www.newsweek.com/key-defeating-covid-19-already-exists-we-need-start-using-it-opinion-1519535

"As professor of epidemiology at Yale School of Public Health, I have authored over 300 peer-reviewed publications and currently hold senior positions on the editorial boards of several leading journals. I am usually accustomed to advocating for positions within the mainstream of medicine, so have been flummoxed to find that, in the midst of a crisis, I am fighting for a treatment that the data fully support but which, for reasons having nothing to do with a correct understanding of the science, has been pushed to the sidelines. As a result, tens of thousands of patients with COVID-19 are dying unnecessarily. Fortunately, the situation can be reversed easily and quickly.

I am referring, of course, to the medication hydroxychloroquine. When this inexpensive oral medication is given very early in the course of illness, before the virus has had time to multiply beyond control, it has shown to be highly effective, especially when given in combination with the antibiotics azithromycin or doxycycline and the nutritional supplement zinc.

On May 27, I published an article in the *American Journal of Epidemiology* (*AJE*) entitled, "Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients that Should be Ramped-Up Immediately as Key to the Pandemic Crisis." That article, published in the world's leading epidemiology journal, **analyzed five studies, demonstrating clear-cut** and **significant benefits to treated patients**, plus other very large studies that showed the medication safety [*emphasis added*]…

Beyond these studies of individual patients, we have seen what happens in large populations when these drugs are used. These have been **'natural experiments'** [*emphasis added*]. In the northern Brazil state of Pará, COVID-19 deaths were increasing exponentially. On April 6, the public hospital network purchased 75,000 doses of azithromycin and 90,000 doses of hydroxychloroquine. Over the next few weeks, authorities began distributing these

medications to infected individuals. Even though new cases continued to occur, on May 22 the death rate started to plummet and is now about one-eighth what it was at the peak.

A reverse natural experiment happened in Switzerland. On May 27, the Swiss national government banned outpatient use of hydroxychloroquine for COVID-19. Around June 10, COVID-19 deaths increased four-fold and remained elevated. On June 11, the Swiss government revoked the ban, and on June 23 the death rate reverted to what it had been beforehand. People who die from COVID-19 live about three to five weeks from the start of symptoms, which makes the evidence of a causal relation in these experiments strong. Both episodes suggest that a combination of hydroxychloroquine and its companion medications reduces mortality and should be immediately adopted as the new standard of care in high-risk patients…

In the future, I believe this misbegotten episode regarding hydroxychloroquine will be studied by sociologists of medicine as a **classic example of how extra-scientific factors overrode clear-cut medical evidence** [*emphasis added*]. But for now, reality demands a clear, scientific eye on the evidence and where it points. For the sake of high-risk patients, for the sake of our parents and grandparents, for the sake of the unemployed, for our economy and for our polity, especially those disproportionally affected, we must start treating immediately."

[996] ***A systematic review on the efficacy and safety of chloroquine for the treatment of COVID-19***
Journal of Critical Care
Andrea Cortegiani, Giulia Ingoglia, *et al*.
June 2020
https://www.sciencedirect.com/science/article/pii/S0883944120303907?via%3Dihub

"**Introduction**: Chloroquine has been used worldwide for more than 70 years, and it is part of the World Health Organization (WHO) model list of essential medicines. It is also cheap and has an established clinical safety profile…

Conclusion: There is sufficient pre-clinical rationale and evidence regarding the effectiveness of chloroquine for treatment of COVID-19 as well as evidence of safety from long-time use in clinical practice for other indications to justify clinical research on the topic."

[997] ***Covid-19 Has Turned Public Health Into a Lethal, Patient-Killing Experimental Endeavor***
Alliance for Human Research Protection
June 20, 2020
https://ahrp.org/covid-19-has-turned-public-health-into-a-lethal-patient-killing-experimental-endeavor/

"On June 14th, Dr. Nass first identified two Covid-19 experiments in which **massive, high toxic doses** – four times higher than usual of hydroxychloroquine – **were being given to severely ill hospitalized patients in intensive care units** [*emphasis added*].

- Solidarity was being conducted by the World Health Organization, on 3500 Covid-19 patients at 400 hospitals, across 35 countries. The hydroxychloroquine arm of the trial was suspended May 25th following the fraudulent Surgisphere report in The Lancet that claimed 35% higher death rates in patients receiving Hydroxychloroquine. But when The Lancet retracted the report, the WHO resumed the Solidarity trial's

hydroxychloroquine arm, on June 3rd. More than 100 countries expressed interest in participating in the trial.

- Recovery is a similar experimental trial conducted in the UK, using very similar doses. It was sponsored by the Wellcome Trust (GlaxoSmithKline) and the Bill and Melinda Gates Foundation and the UK government. The experiment was conducted at Oxford University, on 1,542 patients of these 396 patients (25.7%) died.

Update: After Dr. Nass' discovery was publicly disseminated, the WHO suspended the hydroxychloroquine arm of the trial [*Solidarity*] on Wednesday June 17th."

[998] ***Improving the efficacy of Chloroquine and Hydroxychloroquine against SARS-CoV-2 may require Zinc additives - A better synergy for future COVID-19 clinical trials***
Le Infezioni in Medicina
Mujeeb Olushola Shittu and Olufemi Ifeoluwa Afolami
June 1, 2020
https://www.infezmed.it/media/journal/Vol_28_2_2020_9.pdf

"**Conclusion**: Chloroquine can induce the uptake of zinc into the cytosol of the cell which is capable of inhibiting RNA-dependent RNA polymerase and ultimately halting the replication of coronavirus in the host cell. Currently, there are several clinical trials that are currently underway in several countries of the world to assess the efficacy of chloroquine as an anti-coronavirus agent. Since chloroquine has been widely prescribed for use as an anti-malarial, its safety is not in doubt. In view of the foregoing, clinical trials predicated upon a synergistic administration of Zn supplement with CQ or HCQ against the novel SARS-CoV-2 virus should be considered so that better COVID-19 clinical trial outcomes can be obtained going forward."

[999] **ADDED since 2/8/2008**
Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients That Should Be Ramped Up Immediately as Key to the Pandemic Crisis
American Journal of Epidemiology — Yale School of Public Health
Harvey Risch
May 27, 2020
https://academic.oup.com/aje/article/189/11/1218/5847586

"**Abstract**: … Early outpatient illness is very different from later florid disease requiring hospitalization, and the treatments differ. Evidence about use of HCQ alone, or of HCQ + AZ in inpatients, is irrelevant with regard to the efficacy of HCQ + AZ in early high-risk outpatient disease. Five studies, including 2 controlled clinical trials, have demonstrated **significant major outpatient treatment efficacy**. HCQ + AZ has been used as the standard of care in more than 300,000 older adults with multiple comorbid conditions; the estimated proportion of such patients diagnosed with cardiac arrhythmia attributable to the medications is 47 per 100,000 users, among whom estimated mortality is less than 20% (9/100,000 users), as compared with the 10,000 Americans now dying each week. These medications need to be made widely available and promoted immediately for physicians to prescribe."

[1000] **RETRACTED: *Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis***
The Lancet
Mandeep Mehra, Sapan S. Desai, Frank Ruschitzka, and Amit N. Patel
May 22, 2020
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext

> "**Interpretation**: We were unable to confirm a benefit of hydroxychloroquine or chloroquine, when used alone or with a macrolide, on in-hospital outcomes for COVID-19. Each of these drug regimens was associated with decreased in-hospital survival and an increased frequency of ventricular arrhythmias when used for treatment of COVID-19."

[1001] ***Does zinc supplementation enhance the clinical efficacy of chloroquine/hydroxychloroquine to win today's battle against COVID-19?***
Medical Hypotheses
R. Derwand and M. Scholz
May 6, 2020
https://www.sciencedirect.com/science/article/pii/S0306987720306435

> "**Abstract**: Currently, drug repurposing is an alternative to novel drug development for the treatment of COVID-19 patients. The antimalarial drug chloroquine (CQ) and its metabolite hydroxychloroquine (HCQ) are currently being tested in several clinical studies as potential candidates to limit SARS-CoV-2-mediated morbidity and mortality. CQ and HCQ (CQ/HCQ) inhibit pH-dependent steps of SARS-CoV-2 replication by increasing pH in intracellular vesicles and interfere with virus particle delivery into host cells. Besides direct antiviral effects, **CQ/HCQ specifically target extracellular zinc to intracellular lysosomes where it interferes with RNA-dependent RNA polymerase activity and coronavirus replication** [*emphasis added*]. As zinc deficiency frequently occurs in elderly patients and in those with cardiovascular disease, chronic pulmonary disease, or diabetes, we hypothesize that CQ/HCQ plus zinc supplementation may be more effective in reducing COVID-19 morbidity and mortality than CQ or HCQ in monotherapy. Therefore, CQ/HCQ in combination with zinc should be considered as additional study arm for COVID-19 clinical trials."

[1002] ***Early treatment of COVID-19 patients with hydroxychloroquine and azithromycin: A retrospective analysis of 1061 cases in Marseille, France***
Travel Medicine and Infectious Disease
Matthieu Million, Jean-Christophe Lagier, Didier Raoult, *et al*.
May 5, 2020
https://www.sciencedirect.com/science/article/abs/pii/S1477893920302179

> "**Background**: In France, the combination hydroxychloroquine (HCQ) and azithromycin (AZ) is used in the treatment of COVID-19…
>
> **Results**: A total of 1061 patients were included in this analysis (46.4% male, mean age 43.6 years – range 14–95 years). Good clinical outcome and virological cure were obtained in 973 patients within 10 days (91.7%). Prolonged viral carriage was observed in 47 patients (4.4%) and was associated to a higher viral load at diagnosis ($p < .001$) but viral culture was negative at day 10. All but one, were PCR-cleared at day 15. A poor clinical outcome (PClinO) was observed for 46 patients (4.3%) and 8 died (0.75%) (74–95 years old). All deaths resulted

from respiratory failure and not from cardiac toxicity. Five patients are still hospitalized **(98.7% of patients cured so far)** [*emphasis added*]…

Conclusion: Administration of the HCQ+AZ combination before COVID-19 complications occur is safe and associated with a very low fatality rate in patients.

Introduction: … In a recent international survey conducted among at least 7500 physicians across 30 countries, most of the questioned physicians considered that HCQ and AZ are the two most effective treatments among available therapies for COVID-19."

[1003] ***Clinical and microbiological effect of a combination of hydroxychloroquine and azithromycin in 80 COVID-19 patients with at least a six-day follow up: A pilot observational study***
Travel Medicine and Infectious Disease
Philippe Gautret, Jean-Christophe Lagier, *et al*.
April 11, 2020
https://www.sciencedirect.com/science/article/abs/pii/S1477893920301319

"**Methods**: We conducted an uncontrolled non-comparative observational study in a cohort of 80 relatively mildly infected inpatients treated with a combination of hydroxychloroquine and azithromycin over a period of at least three days, with three main measurements: clinical outcome, contagiousness as assessed by PCR and culture, and length of stay in infectious disease unit (IDU).

Results: **All patients improved clinically** except one 86 year-old patient who died, and one 74 year-old patient still in intensive care. A rapid fall of nasopharyngeal viral load was noted, with 83% negative at Day7, and 93% at Day8 [*emphasis added*]. Virus cultures from patient respiratory samples were negative in 97.5% of patients at Day5. Consequently patients were able to be rapidly discharged from IDU with a mean length of stay of five days…

Introduction: … According to an online survey conducted at the end of March, 33% of an international panel of physicians reported personally prescribing (or seeing colleagues prescribe) hydroxychloroquine (or chloroquine), and 41% reported the same for azithromycin (or similar antibiotics) to fight COVID-19. In addition, of those who have treated COVID-19 patients, **37% believe that hydroxychloroquine** (or chloroquine) **is the most effective therapy against the disease**, and **32% believe the same for azithromycin** [*emphasis added*] (or similar antibiotics)."

[1004] ***Largest Statistically Significant Study by 6,200 Multi-Country Physicians on COVID-19 Uncovers Treatment Patterns and Puts Pandemic in Context***
Sermo
April 2, 2020
https://www.sermo.com/press-releases/largest-statistically-significant-study-by-6200-multi-country-physicians-on-covid-19-uncovers-treatment-patterns-and-puts-pandemic-in-context/

"To create a centralized and dynamic knowledge base, Sermo, the largest healthcare data collection company and global social platform for physicians, leveraged its capabilities to publish results of a COVID-19 study with more than 6,200 physicians in 30 countries…

Treatments & Efficacy

- The three most commonly prescribed treatments amongst COVID-19 treaters are 56% analgesics, 41% Azithromycin, and 33% Hydroxychloroquine…
- **Hydroxychloroquine was overall chosen as the most effective therapy** amongst COVID-19 treaters from a list of 15 options (37% of COVID-19 treaters) [*emphasis added*]"

[1005] ***Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial***
International Journal of Antimicrobial Agents
Philippe Gautret, Jean-Christophe Lagier, *et al*.
March 20, 2020
https://www.sciencedirect.com/science/article/abs/pii/S0924857920300996

"**Conclusion**: Despite its small sample size, our survey shows that hydroxychloroquine treatment is significantly associated with viral load reduction/disappearance in COVID-19 patients and its effect is reinforced by azithromycin."

[1006] ***In Vitro Antiviral Activity and Projection of Optimized Dosing Design of Hydroxychloroquine for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)***
Clinical Infectious Diseases
Xueting Yao, Fei Ye, *et al*.
March 9, 2020
https://academic.oup.com/cid/article/71/15/732/5801998

"**Background**: … Chloroquine has been sporadically used in treating SARS-CoV-2 infection. Hydroxychloroquine shares the same mechanism of action as chloroquine, but its more tolerable safety profile makes it the preferred drug to treat malaria and autoimmune conditions. We propose that the immunomodulatory effect of hydroxychloroquine also may be useful in controlling the cytokine storm that occurs late phase in critically ill patients with SARS-CoV-2…

Results: Hydroxychloroquine (EC50 = 0.72 μM) was found to be more potent than chloroquine (EC50 = 5.47 μM) in vitro."

[1007] ***Chloroquine is a potent inhibitor of SARS coronavirus infection and spread***
Virology Journal
Martin J. Vincent, Eric Bergeron, *et al*.
August 22, 2005
https://virologyj.biomedcentral.com/articles/10.1186/1743-422X-2-69

"**Background**: Severe acute respiratory syndrome (SARS) is caused by a newly discovered coronavirus (SARS-CoV). No effective prophylactic or post-exposure therapy is currently available.

Results: We report, however, that chloroquine has strong antiviral effects on SARS-CoV infection of primate cells. These inhibitory effects are observed when the cells are treated with the drug either before or after exposure to the virus, suggesting both prophylactic and

therapeutic advantage…

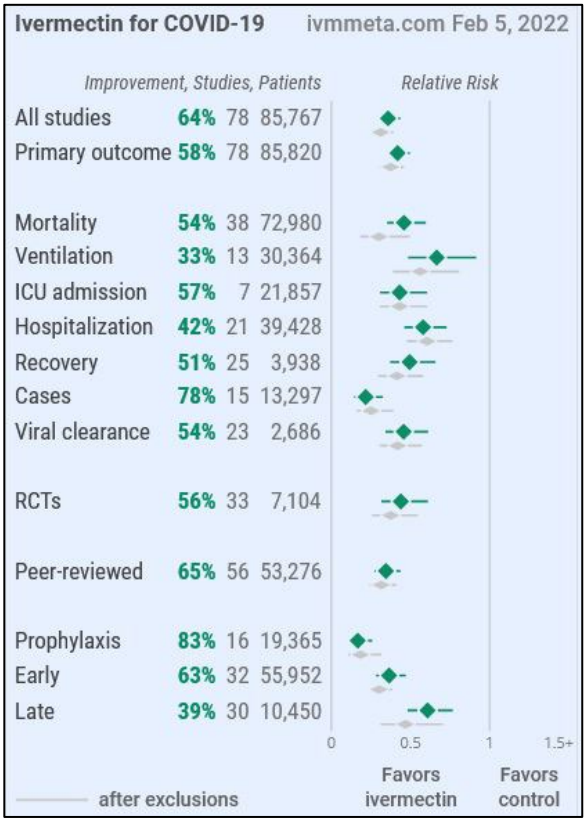
Conclusion: Chloroquine is effective in preventing the spread of SARS CoV in cell culture. Favorable inhibition of virus spread was observed when the cells were either treated with chloroquine prior to or after SARS CoV infection."

Ivermectin

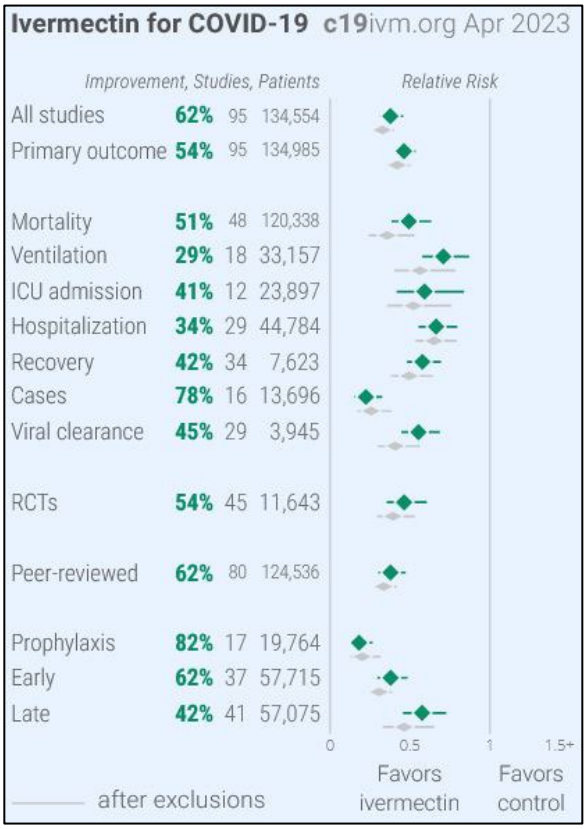
[1008] ***#Ivermectin for COVID-19: Real-time meta-analysis of 78 studies***
February 2, 2022, Version 175
https://ivmmeta.com/

"Statistically significant improvements are seen for mortality, ventilation, ICU admission, hospitalization, recovery, cases, and viral clearance. All remain significant after exclusions. 50 studies from 46 independent teams in 21 different countries show statistically significant improvements in isolation (38 primary outcome, 35 most serious outcome).

Meta analysis using the most serious outcome reported shows **63% [53-72%] and 83% [74-89%] improvement** for early treatment and prophylaxis [*emphasis added*], with similar results after exclusion based sensitivity analysis (excluding all GMK/BBC team studies), for primary outcomes, for peer-reviewed studies, and for RCTs [*randomized controlled trials*]."



ADDED since 2/8/2022
February 23, 2023, Version 175



[1009] ***One Page Summary of the Clinical Trials Evidence for Ivermectin in COVID-19***
Front Line COVID-19 Critical Care (FLCCC) Alliance
January 11, 2021
https://covid19criticalcare.com/wp-content/uploads/2020/12/One-Page-Summary-of-the-Clinical-Trials-Evidence-for-Ivermectin-in-COVID-19.pdf

> "Ivermectin, an anti-parasitic medicine whose discovery won the Nobel Prize in 2015, has proven, highly potent, anti-viral and anti-inflammatory properties in laboratory studies. In the past 4 months, numerous, controlled clinical trials from multiple centers and countries worldwide are reporting consistent, large improvements in COVID-19 patient outcomes when treated with ivermectin. Our comprehensive scientific review of these referenced trials can be found on the Open Science Foundation pre-print server here: https://osf.io/wx3zn/."

[1010] ***Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations***
Journal of Antibiotics (Nature)
Andy Crump
February 15, 2017
https://www.nature.com/articles/ja201711

> "**Abstract**: Over the past decade, the global scientific community have begun to recognize the unmatched value of an extraordinary drug, ivermectin, that originates from a single microbe unearthed from soil in Japan. Work on ivermectin has seen its discoverer, Satoshi Ōmura, of Tokyo's prestigious Kitasato Institute, receive the 2014 Gairdner Global Health Award and the 2015 Nobel Prize in Physiology or Medicine, which he shared with a collaborating partner in the discovery and development of the drug, William Campbell of Merck & Co. Incorporated. Today, ivermectin is continuing to surprise and excite scientists, offering more and more promise to help improve global public health by treating a diverse range of diseases, with its **unexpected potential as an antibacterial, antiviral** and **anti-cancer agent** being particularly extraordinary [*emphasis added*]."

[1011] ***Ivermectin: A Drug Worthy of a Nobel Prize, but Inaccessible for Those Who Need It***
Barcelona Institute of Global Health
Jose Munoz
October 22, 2015
https://www.isglobal.org/en/healthisglobal/-/custom-blog-portlet/ivermectina-un-medicamento-de-nobel-pero-poco-accesible/91127/0

> "The Japanese scientist Satoshi Omura has recently received the Nobel Prize in Physiology and Medicine for his discovery of ivermectin more than 30 years ago. Invermectin is best known for its extraordinarily broad spectrum of activity against nematodes, the roundworms that cause a large proportion of the most common neglected diseases on our planet. It is used to treat millions of people at risk of contracting devastating diseases, such as onchocerciasis and lymphatic filariasis, and also plays an important role in the control of intestinal helminth infections. Because of its excellent safety profile and broad spectrum of activity, ivermectin is catalogued by the World Health Organisation as an essential medicine and is **regarded by many as a 'magic bullet' for global health** [*emphasis added*]."

[1012] ***2015 Nobel Prize in Physiology or Medicine***
Nobel Assembly
2015
https://www.nobelprize.org/uploads/2018/06/press-29.pdf

> "Diseases caused by parasites have plagued humankind for millennia and constitute a major global health problem. In particular, parasitic diseases affect the world's poorest populations and represent a huge barrier to improving human health and wellbeing. This year's Nobel Laureates have developed therapies that have revolutionized the treatment of some of the most devastating parasitic diseases.
>
> William C. Campbell and Satoshi Ōmura discovered a new drug, Avermectin, the derivatives of which have radically lowered the incidence of River Blindness and Lymphatic Filariasis, as well as showing efficacy against an expanding number of other parasitic diseases…

Today the Avermectin-derivative Ivermectin is used in all parts of the world that are plagued by parasitic diseases. Ivermectin is highly effective against a range of parasites, has limited side effects and is freely available across the globe. The importance of Ivermectin for improving the health and wellbeing of millions of individuals with River Blindness and Lymphatic Filariasis, primarily in the poorest regions of the world, is immeasurable. Treatment is so successful that these diseases are on the verge of eradication, which would be a major feat in the medical history of humankind…

The global impact of their discoveries and the resulting benefit to mankind are immeasurable."

[1013] ***WHO Model List of Essential Medicines, 19th edition***
World Health Organization (WHO)
Amended August 2015
https://www.who.int/selection_medicines/committees/expert/20/EML_2015_FINAL_amended_AUG2015.pdf?ua=1

p. 6: "6. Anti-Infective Medicines… 6.1 Anthelminthics… 6.1.2 Antifilarials… ivermectin"

[1014] ***Ivermectin, 'Wonder drug' from Japan: the human use perspective***
Proceedings of the Japan Academy, Series B, Physical and Biological Sciences
Andy Crump and Satoshi Omura
February 10, 2011
https://www.jstage.jst.go.jp/article/pjab/87/2/87_2_13/_article

"**Abstract**: Discovered in the late-1970s, the pioneering drug ivermectin, a dihydro derivative of avermectin—originating solely from a single microorganism isolated at the Kitasato Intitute, Tokyo, Japan from Japanese soil—has had an immeasurably beneficial impact in improving the lives and welfare of billions of people throughout the world. Originally introduced as a veterinary drug, it kills a wide range of internal and external parasites in commercial livestock and companion animals. It was quickly discovered to be ideal in combating two of the world's most devastating and disfiguring diseases which have plagued the world's poor throughout the tropics for centuries. It is now being used free-of-charge as the sole tool in campaigns to eliminate both diseases globally. It has also been **used to successfully overcome several other human diseases** and **new uses for it are continually being found**. This paper looks in depth at the events surrounding ivermectin's passage from being a huge success in Animal Health into its widespread use in humans, a development which has led many to describe it as a **'wonder' drug** [*emphasis added*]."

Note: The citations below are presented in reverse, chronological order.

[1015] **ADDED since 2/8/2022**

Regular Use of Ivermectin as Prophylaxis for COVID-19 Led Up to a 92% Reduction in COVID-19 Mortality Rate in a Dose-Response Manner: Results of a Prospective Observational Study of a Strictly Controlled Population of 88,012 Subjects

Cureus

Lucy Kerr, Fernando Baldi, *et al*.

August 31, 2022

https://www.cureus.com/articles/111851-regular-use-of-ivermectin-as-prophylaxis-for-covid-19-led-up-to-a-92-reduction-in-covid-19-mortality-rate-in-a-dose-response-manner-results-of-a-prospective-observational-study-of-a-strictly-controlled-population-of-88012-subjects

"**Background**: We have previously demonstrated that ivermectin used as prophylaxis for coronavirus disease 2019 (COVID-19), irrespective of the regularity, in a strictly controlled citywide program in Southern Brazil (Itajaí, Brazil), was associated with reductions in COVID-19 infection, hospitalization, and mortality rates. In this study, our objective was to determine if the regular use of ivermectin impacted the level of protection from COVID-19 and related outcomes, reinforcing the efficacy of ivermectin through the demonstration of a dose-response effect.

Results: Among 223,128 subjects from the city of Itajaí, 159,560 were 18 years old or up and were not infected by COVID-19 until July 7, 2020, from which 45,716 (28.7%) did not use and 113,844 (71.3%) used ivermectin. Among ivermectin users, 33,971 (29.8%) used irregularly (up to 60 mg) and 8,325 (7.3%) used regularly (more than 180 mg)… The hospitalization rate was reduced by 100% in regular users compared to both irregular users and non-users ($p < 0.0001$), and by 29% among irregular users compared to non-users (RR: 0.781; 95% CI: 0.49-1.05; $p = 0.099$). Mortality rate was 92% lower in regular users than non-users (RR: 0.08; 95% CI: 0.02-0.35; $p = 0.0008$) and 84% lower than irregular users (RR: 0.16; 95% CI: 0.04-0.71; $p = 0.016$), while irregular users had a 37% lower mortality rate reduction than non-users (RR: 0.67; 95% CI: 0.40-0.99; $p = 0.049$). Risk of dying from COVID-19 was 86% lower among regular users than non-users (RR: 0.14; 95% CI: 0.03-0.57; $p = 0.006$), and 72% lower than irregular users (RR: 0.28; 95% CI: 0.07-1.18; $p = 0.083$), while irregular users had a 51% reduction compared to non-users (RR: 0.49; 95% CI: 0.32-0.76; $p = 0.001$).

Conclusion: **Non-use of ivermectin was associated with a 12.5-fold increase in mortality rate** and a seven-fold increased risk of dying from COVID-19 compared to the regular use of ivermectin. This dose-response efficacy reinforces the prophylactic effects of ivermectin against COVID-19."

[1016] **ADDED since 2/8/2022**

Changes in SpO2 on Room Air for 34 Severe COVID-19 Patients after Ivermectin-Based Combination Treatment: 62% Normalization within 24 Hours

Biologics

Jacqueline C. Stone, Pisirai Ndarukwa, *et al*.

August 31, 2022

https://www.mdpi.com/2673-8449/2/3/15

"**Abstract**: The emergence of COVID-19 in March 2020 challenged Zimbabwe to respond with limited medical facilities and therapeutic options. Based on early clinical indications of efficacy for the macrocyclic lactone, Ivermectin (IVM), against COVID-19, IVM-based combination treatments were deployed to treat it. Oxygen saturation (SpO2) data were retrospectively analyzed for 34 severe, hypoxic COVID-19 patients all on room air (without supplemental oxygen). The patients, median age 56.5, were treated at clinics or at home between August 2020 and May 2021. All but three of these 34 patients had significantly increased SpO2 values within 24 h after the first IVM dose. The **mean increase in SpO2** as a percentage of full normalization to SpO2 = 97 **was 55.1% at +12 h** and **62.3% at +24 h** after the first IVM dose (paired t-test, $p < 0.0000001$). These results parallel similar sharp, rapid increases in SpO2, all on room air, for 24 mostly severe COVID-19 patients in the USA (California) who were given an IVM-based combination treatment. All patients in both of these critical series recovered. These rapid increases in SpO2 values after IVM treatment stand in sharp contrast to declines in SpO2 and associated pulmonary function through the second week following the onset of moderate or severe COVID-19 symptoms under standard care."

[1017] **ADDED since 2/8/2022**

Insights from a computational analysis of the SARS-CoV-2 Omicron variant: Host-pathogen interaction, pathogenicity and possible therapeutics

Cornell University

Sorwer Alam Parvez, Manash Kumar Saha, *et al*.

January 20, 2022

https://arxiv.org/ftp/arxiv/papers/2201/2201.08176.pdf

"**Abstract**: … Most of the tested drugs were proven to be effective. Nirmatrelvir (Paxlovid), MPro 13b, and Lopinavir displayed increased effectiveness and efficacy, while **Ivermectin showed the best result** against Omicron [*emphasis added*]…

Analysis of the Effectiveness of Promising Drugs: We analyzed ten promising drugs targeting the main (3CL) protease protein of SARS-CoV-2 including Nirmatrelvir, Ritonvir, Ivermectin, Lopinavir, Boceprevir, MPro 13b, MPro N3, GC373, GC376, and PF-0083523."

[1018] ***Ivermectin Prophylaxis Used for COVID-19: A Citywide, Prospective, Observational Study of 223,128 Subjects Using Propensity Score Matching***
Cureus
Lucy Kerr, Flavio A. Cadegiani, *et al*.
January 15, 2022
https://www.cureus.com/articles/82162-ivermectin-prophylaxis-used-for-covid-19-a-citywide-prospective-observational-study-of-223128-subjects-using-propensity-score-matching

> "**Materials and methods**: We analyzed data from a prospective, observational study of the citywide COVID-19 prevention with ivermectin program, which was conducted between July 2020 and December 2020 in Itajaí, Brazil…
>
> **Results**: Of the 223,128 citizens of Itajaí considered for the study, a total of 159,561 subjects were included in the analysis: 113,845 (71.3%) regular ivermectin users and 45,716 (23.3%) non-users... The regular use of ivermectin led to a **68% reduction in COVID-19 mortality** (25 [0.8%] versus 79 [2.6%] among ivermectin non-users; RR, 0.32; 95% CI, 0.20-0.49; p < 0.0001). When adjusted for residual variables, reduction in mortality rate was 70% (RR, 0.30; 95% CI, 0.19-0.46; p < 0.0001). There was a **56% reduction** in hospitalization rate [*emphasis added*] (44 versus 99 hospitalizations among ivermectin users and non-users, respectively; RR, 0.44; 95% CI, 0.31-0.63; p < 0.0001). After adjustment for residual variables, reduction in hospitalization rate was 67% (RR, 0.33; 95% CI, 023-0.66; p < 0.0001).
>
> **Conclusion**: In this large PSM study, regular use of ivermectin as a prophylactic agent was associated with significantly reduced COVID-19 infection, hospitalization, and mortality rates."

[1019] ***Ivermectin prophylaxis used for COVID-19 reduces COVID-19 infection and mortality rates: A 220,517-subject, populational-level retrospective citywide observational study***
Corpometria Institute (Brazil)
Lucy Kerr, Flavio A. Cadegiani, *et al*.
December 11, 2021
https://www.researchgate.net/publication/356962821_Ivermectin_prophylaxis_used_for_COVID-19_reduces_COVID-19_infection_and_mortality_rates_A_220517-subject_populational-level_retrospective_citywide

> "**Results**: A total of 220,517 subjects were included in the analysis; 133,051 (60.3%) ivermectin users and 87,466 (39.7%) non-users… A total of 62 deaths (1.4% mortality rate) occurred among users and 79 deaths(2.6% mortality rate) among non-users, showing a **48% reduction in mortality rate** [*emphasis added*] (RR, 0,52; 95%CI, 0.37 – 0.72; p = 0.0001). Risk of dying from COVID-19 among ivermectin users was 45% lower than non-users (RR, 0.55; 95%CI, 0.40 – 0.77; p = 0.0004)"

[1020] ***Ivermectin as a SARS-CoV-2 Pre-Exposure Prophylaxis Method in Healthcare Workers: A Propensity Score-Matched Retrospective Cohort Study***
Cureus
Jose Morgenstern, Jose N. Redondo, *et al*.
August 26, 2021
https://www.cureus.com/articles/63131-ivermectin-as-a-sars-cov-2-pre-exposure-prophylaxis-method-in-healthcare-workers-a-propensity-score-matched-retrospective-cohort-study

"**Background**: Ivermectin is a drug that has been shown to be active against coronavirus disease 19 (COVID-19) in previous studies. Healthcare personnel are highly exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Therefore, we decided to offer them ivermectin as a pre-exposure prophylaxis (PrEP) method…

Results: In 28 days of follow-up, **significant protection of ivermectin** preventing the infection from SARS-CoV-2 was observed: 1.8% compared to those who did not take it (6.6%; p-value = 0.006), with a **risk reduction of 74%** [*emphasis added*]."

[1021] **Press conference: *Tokyo Medical Association President recommends Ivermectin to all doctors***
Tokyo Medical Association
August 26, 2021
https://odysee.com/@snowchindy:f/video_2021-08-27_19-46-39:3

"In Africa, if we compare countries distributing Ivermectin once a year with countries which do not give ivermectin. I mean, they don't give ivermectin to prevent Covid, but to prevent parasitic diseases, but anyway, if we look at Covid numbers in countries that give ivermectin, the number of cases is 134.4 per 100,000, and the number of deaths is 2.2 per 100,000. Now African countries which do not distribute ivermectin – 950.6 cases per 100,000 and 29.3 deaths per 100,000. I believe the difference is clear. Of course, one cannot conclude that ivermectin is effective only on the basis of these figures, but when we have all these elements, we cannot say that ivermectin is absolutely not effective, at least not me. We can do other studies to confirm its efficacy, but we are in a crisis situation. With regard to the use of ivermectin, it is obviously necessary to obtain the informed consent of the patients, and I think we're in a situation where we can afford to give them this treatment."

[1022] ***Summary of the Evidence for Ivermectin in COVID-19***
Front Line COVID-19 Critical Care (FLCCC) Alliance
August 4, 2021
https://covid19criticalcare.com/wp-content/uploads/2021/08/SUMMARY-OF-THE-EVIDENCE-BASE.pdf

"Ivermectin is an anti-parasite medicine whose discovery won the Nobel Prize in 2015 for its impacts in ridding large parts of the globe of parasitic diseases via distribution of over 3.7 billion doses within public health campaigns since 1987.

Since 2012, numerous in-vitro studies began to report highly potent anti-viral effects against a diverse array of viruses, including SARS-CoV-2 along with numerous anti-inflammatory and immuno-modulating effects…

Currently, as of August 4, 2021, the totality of the evidence is as follows: …

Conclusion: Based on the totality of the existing evidence above, the FLCCC strongly recommends ivermectin be used in both the prevention and treatment of all phases of COVID-19 in both vaccinated and unvaccinated populations."

[1023] ***Ivermectin: a multifaceted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, COVID-19***
New Microbes and New Infections
A.D. Santin, D.E. Schelm, *et al*.
August 3, 2021
https://www.sciencedirect.com/science/article/pii/S2052297521000883?via%3Dihub

"**Abstract**: In 2015, the Nobel Committee for Physiology or Medicine, in its only award for treatments of infectious diseases since six decades prior, honoured the discovery of ivermectin (IVM), a multifaceted drug deployed against some of the world's most devastating tropical diseases. Since March 2020, when IVM was first used against a new global scourge, COVID-19, more than 20 randomized clinical trials (RCTs) have tracked such inpatient and outpatient treatments. **Six of seven meta-analyses** of IVM treatment RCTs reporting in 2021 **found notable reductions in COVID-19 fatalities,** with a mean 31% relative risk of mortality vs. controls [*emphasis added*]. During mass IVM treatments in Peru, excess deaths fell by a mean of 74% over 30 days in its ten states with the most extensive treatments. Reductions in deaths correlated with the extent of IVM distributions in all 25 states with $p < 0.002$. Sharp reductions in morbidity using IVM were also observed in two animal models, of SARS-CoV-2 and a related betacoronavirus. The indicated biological mechanism of IVM, competitive binding with SARS-CoV-2 spike protein, is likely non-epitope specific, possibly yielding full efficacy against emerging viral mutant strains…

Introduction: … Dr Satoshi Omura, the Nobel co-laureate for the discovery of IVM, and colleagues conducted a comprehensive review of IVM clinical activity against COVID-19, concluding that **the preponderance of the evidence demonstrated major reductions in mortality and morbidity**. Our review of that evidence, updated with consideration of several new studies, supports the same conclusion [*emphasis added*]."

[1024] ***Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines***
American Journal of Therapeutics
Andrew Bryant, Theresa A. Lawrie, *et al*.
July/August 2021
https://journals.lww.com/americantherapeutics/Fulltext/2021/08000/Ivermectin_for_Prevention_and_Treatment_of.7.aspx

"**Background**: Repurposed medicines may have a role against the SARS-CoV-2 virus. The antiparasitic ivermectin, with antiviral and anti-inflammatory properties, has now been tested in numerous clinical trials.

Data sources: We searched bibliographic databases up to April 25, 2021. Two review authors sifted for studies, extracted data, and assessed risk of bias. Meta-analyses were conducted and certainty of the evidence was assessed using the GRADE approach and additionally in trial sequential analyses for mortality. Twenty-four randomized controlled trials involving 3406 participants met review inclusion.

Conclusions: Moderate-certainty evidence finds that **large reductions in COVID-19 deaths** are possible using ivermectin [*emphasis added*]. Using ivermectin early in the clinical course may reduce numbers progressing to severe disease. The apparent safety and low cost suggest that ivermectin is likely to have a significant impact on the SARS-CoV-2 pandemic globally.

All-cause mortality: Meta-analysis of 15 trials, assessing 2438 participants, found that ivermectin reduced the risk of death by an average of 62% (95% CI 27%–81%) compared with no ivermectin treatment."

[1025] ***COVID-19 Treatment Guidelines***
National Institutes of Health (NIH)
Updated July 8, 2021
https://www.covid19treatmentguidelines.nih.gov/tables/table-2e/

"Table 2e. Characteristics of Antiviral Agents That Are Approved or Under Evaluation for the Treatment of COVID-19

Ivermectin

- Dosing Regimens. The dose most commonly used in clinical trials is IVM 0.2–0.6 mg/kg PO given as a single dose or as a once-daily dose for up to 5 days
- Adverse Events. Generally well tolerated"

[1026] ***Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infection***
Open Forum Infectious Diseases (Oxford)
Andrew Hill, Anna Garratt, *et al*.
July 6, 2021
https://academic.oup.com/ofid/advance-article/doi/10.1093/ofid/ofab358/6316214

"**Abstract**: … This meta-analysis investigated ivermectin in 24 randomized clinical trials (3328 patients) identified through systematic searches of PUBMED, EMBASE, MedRxiv and trial registries. Ivermectin was associated with reduced inflammatory markers (C-Reactive Protein, d-dimer and ferritin) and faster viral clearance by PCR. Viral clearance was treatment dose- and duration-dependent. In 11 randomized trials of moderate/severe infection, there was a **56% reduction in mortality** [*emphasis added*] (Relative Risk 0.44 [95%CI 0.25-0.77]; p=0.004; 35/1064 (3%) deaths on ivermectin; 93/1063 (9%) deaths in controls) with favorable clinical recovery and reduced hospitalization."

[1027] ***Antiviral effect of high-dose ivermectin in adults with COVID-19: A proof-of-concept randomized trial***
EClinicalMedicine – The Lancet
Alejandro Krolewiecki, Adrian Lifschitz, *et al*.
June 17, 2021
https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00239-X/fulltext

"**Findings**: 45 participants were recruited (30 to IVM and 15 controls) between May 18 and September 9, 2020. There was no difference in viral load reduction between groups but a significant difference was found in patients with higher median plasma IVM levels (72% IQR 59–77) versus untreated controls (42% IQR 31–73) (p = 0·004). Mean ivermectin plasma

concentration levels correlated with viral decay rate (r: 0·47, p = 0·02). Adverse events were similar between groups…

Interpretation: A concentration dependent antiviral activity of oral high-dose IVM was identified at a dosing regimen that was well tolerated."

[1028] **RETRACTED: *The mechanisms of action of Ivermectin against SARS-CoV-2: An evidence-based clinical review article***
The Journal of Antibiotics
Asiya Kamber Zaidi and Puya Dehgani-Mobaraki
June 15, 2021
https://www.nature.com/articles/s41429-021-00430-5

"**Abstract**: Considering the urgency of the ongoing COVID-19 pandemic, detection of various new mutant strains and future potential re-emergence of novel coronaviruses, repurposing of approved drugs such as Ivermectin could be worthy of attention. This evidence-based review article aims to discuss the mechanism of action of ivermectin against SARS-CoV-2 and summarizing the available literature over the years. A schematic of the key cellular and biomolecular interactions between Ivermectin, host cell, and SARS-CoV-2 in COVID-19 pathogenesis and prevention of complications have been proposed…

Introduction: … Several doctor-initiated clinical trial protocols that aimed to evaluate outcomes, such as reduction in mortality figures, shortened length of intensive care unit stay and/or hospital stay and elimination of the virus with ivermectin use have been registered at the US ClinicalTrials.gov. Real-time data is also available with a meta-analysis of 55 studies to date. As per data available on 16 May 2021, 100% of 36 early treatment and prophylaxis studies report positive effects (96% of all 55 studies). Of these, 26 studies show statistically significant improvements in isolation. Random effects meta-analysis with pooled effects using the most serious outcome reported 79% and 85% improvement for early treatment and prophylaxis respectively… Statistically significant improvements were seen for mortality, ventilation, hospitalization, cases, and viral clearance. **100% of the 17 Randomized Controlled Trials (RCTs) for early treatment and prophylaxis report positive effects**, with an estimated improvement of 73% and 83% respectively… and 93% of all 28 RCTs [*emphasis added*]…

This article aims to discuss the mechanism of action by summarizing the in vitro and in vivo evidence demonstrating the role of Ivermectin in COVID-19 as per the available literature over the years…"

Fig 1. notes: Ivermectin; IVM (red block) inhibits and disrupts binding of the SARS-CoV-2 S protein at the ACE-2 receptors (green)."

[1029] ***Good news in La Pampa: Preliminary results of ivermectin treatments in Covid-19 patients are encouraging***
Bichos de campo
Field Bugs
June 9, 2021
https://bichosdecampo.com/buenas-noticias-en-la-pampa-son-alentadores-los-resultados-preliminares-de-tratamientos-con-ivermectina-en-pacientes-con-covid-19/

> "Ivermectin, an antiparasitic well known to all livestock producers, was shown to have verifiable results for the treatment of Covid-19 symptoms in a study carried out in the province of La Pampa…
>
> [I]t was evidenced that in people over 40 years of age the frequency of hospitalization in intensive care was close to 40% lower in those who received ivermectin, while the development of severe forms of the disease (defined from admission to intensive care or death of patients) was 35% less frequent in treated subjects than in those who did not participate in the program."

[1030] ***Ivermectin: Provide partial monitoring results in expanded use in positive patients***
Pagina 16
June 2021
http://www.pagina16.com.ar/ivermectina-brindan-resultados-parciales-de-monitoreo-en-el-uso-ampliado-en-pacientes-positivos/

> "From January to June of this year, of 4,000 patients who were included in the monitoring, carried out by [*Argentina's*] Ministry of Public Health of Misiones together with scientific institutions, in the expanded use of Ivermectin in positive patients, 2,500 of them are actively monitoring and recording information, according to data from the first partial report of the Ivermis T monitoring…
>
> **Efficacy**: … [A] 3.5-fold decrease in cases requiring hospitalization and a 1.5-fold decrease in fatal cases is observed in the population treated with Ivermectin."

[1031] ***Favorable outcome on viral load and culture viability using Ivermectin in early treatment of non-hospitalized patients with mild COVID-19 – A double-blind, randomized placebo-controlled trial***
Sheba Medical Center and Ministry of Health (Israel)
Asaf Biber, Michal Mandelboim, *et al*.
May 31, 2021
https://www.medrxiv.org/content/10.1101/2021.05.31.21258081v1.full-text

> "**Background**: we conducted a double blinded randomized control trial to assess whether Ivermectin can shorten viral shedding, in non-hospitalized patients at the early stage of COVID-19 infection.
>
> **Discussion**: In this double-blind, randomized trial with mild COVID-19 patients, ivermectin significantly reduced time of viral shedding and affected viral viability when initiated at the first week after evidence of infection. Our primary endpoint was to show the benefit of ivermectin on day six (three days after ending treatment) which was achieved with 72% of samples being non-infectious (Ct>30) in comparison to 50% among the placebo group (OR 2·6)."

[1032] ***Uttar Pradesh government says early use of Ivermectin helped to keep positivity, deaths low***
The Indian Express
Maulshree Seth
May 12, 2021
https://indianexpress.com/article/cities/lucknow/uttar-pradesh-government-says-ivermectin-helped-to-keep-deaths-low-7311786/

> "A year after the country's first Covid-19 cluster, with 5 cases, was reported in Agra district, the Uttar Pradesh government has claimed that it was the first state to have introduced a large-scale 'prophylactic and therapeutic' use of Ivermectin and added that the drug helped the state to maintain a lower fatality and positivity rate as compared to other states…
>
> 'Uttar Pradesh was the first state in the country to introduce large-scale prophylactic and therapeutic use of Ivermectin. In May-June 2020, a team at Agra, led by Dr Anshul Pareek, administered Ivermectin to all RRT team members in the district on an experimental basis. It was observed that none of them developed Covid-19 despite being in daily contact with patients who had tested positive for the virus,' Uttar Pradesh State Surveillance Officer Vikssendu Agrawal said…
>
> Claiming that timely introduction of Ivermectin since the first wave has helped the state maintain a relatively low positivity rate despite its high population density, he [*Agrawal*] said, 'Despite being the state with the largest population base and a high population density, we have maintained a relatively low positivity rate and cases per million of population.'"

[1033] ***Ivermectin and the odds of hospitalization due to COVID-19: evidence from a quasi-experimental analysis based on a public intervention in Mexico City***
SocArXiv Papers
Jose Merino, Victor Hugo Borja, *et al*.
May 3, 2021
https://osf.io/preprints/socarxiv/r93g4/

> "**Objective**: To measure the effect of Mexico City's population-level intervention –an ivermectin-based Medical Kit—in hospitalizations during the COVID-19 pandemic…
>
> **Results**: We found a significant reduction in hospitalizations among patients who received the ivermectin-based medical kit; the **range of the effect is 52%-76%** depending on model specification [*emphasis added*]."

[1034] ***Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19***
American Journal of Therapeutics
Pierre Kory, Gianfranco Umberto Meduri, Joseph Varon, Jose Iglesias, and Paul Marik
April 22, 2021
https://journals.lww.com/americantherapeutics/Fulltext/2021/06000/Review_of_the_Emerging_Evidence_Demonstrating_the.4.aspx

> "**Conclusions**: Meta-analyses based on 18 randomized controlled treatment trials of ivermectin in COVID-19 have found **large, statistically significant reductions in mortality**, time to clinical recovery, and time to viral clearance [*emphasis added*]. Furthermore, results

from numerous controlled prophylaxis trials report significantly reduced risks of contracting COVID-19 with the regular use of ivermectin. Finally, the many examples of ivermectin distribution campaigns leading to rapid population-wide decreases in morbidity and mortality indicate that an oral agent effective in all phases of COVID-19 has been identified."

[1035] ***Repurposing Ivermectin for COVID-19: Molecular Aspects and Therapeutic Possibilities***
Frontiers in Immunology
Zena Wehbe, Maya Wehbe, *et al*.
March 30, 2021
https://www.frontiersin.org/articles/10.3389/fimmu.2021.663586/full

"In this review, we delineate the story of how this antiparasitic drug was eventually identified as a potential treatment option for COVID-19. We review SARS-CoV-2 lifecycle, the role of the nucleocapsid protein, the turning points in past research that provided initial 'hints' for IVM's antiviral activity and its molecular mechanism of action- and finally, we culminate with the current clinical findings…

Concluding Remarks and Perspectives: The available data from IVM clinical trials lack uniformity and have not established the optimal anti-viral dose. However, the evidence does support its safety and efficacy in improving survival rates, especially compared to the other aforementioned drugs. It is important to note that past research has demonstrated the importance of combined, rather than anti-viral monotherapy. Indeed, the use of a single drug does not efficiently suppress long-term replication of the virus. As evident by the ongoing clinical trials for the treatment of COVID-19, the most efficient decrease in mortality (0%) was largely a result of multiple prescribed drugs including IVM, hydroxychloroquine and azithromycin or IVM and doxycyline Table 1."

[1036] ***Ivermectin reduces in vivo coronavirus infection in a mouse experimental model***
Scientific Reports
A.P. Arevalo, R. Pagotta, *et al*.
March 30, 2021
https://www.nature.com/articles/s41598-021-86679-0/

"**Abstract**: The objective of this study was to test the effectiveness of ivermectin for the treatment of mouse hepatitis virus (MHV), a type 2 family RNA coronavirus similar to SARS-CoV-2… Overall, the results demonstrated that viral infection induced typical MHV-caused disease, with the livers showing severe hepatocellular necrosis surrounded by a severe lymphoplasmacytic inflammatory infiltration associated with a high hepatic viral load (52,158 AU), while mice treated with ivermectin showed a better health status with a lower viral load (23,192 AU; $p < 0.05$), with only a few having histopathological liver damage ($p < 0.05$)… In conclusion, ivermectin diminished the MHV viral load and disease in the mice, being a useful model for further understanding this therapy against coronavirus diseases."

[1037] ***Why COVID-19 is not so spread in Africa: How does Ivermectin affect it?***
Tanioka Clinic & National Institute of Sensory Organs (Japan)
Hisaya Tanioka, Sayaka Tanioka, and Kimitaka Kaga
March 26, 2021
https://www.medrxiv.org/content/10.1101/2021.03.26.21254377v1.full.pdf

"**Background**: Scientists have so far been unable to determine the reason for the low number of COVID-19 cases in Africa.

Objective: To evaluate the impact of ivermectin interventions for onchocerciasis on the morbidity, mortality, recovery, and fatality rates caused by COVID-19.

Conclusions: The morbidity and mortality in the onchocerciasis endemic countries are lesser than those in the non-endemic ones. The community-directed onchocerciasis treatment with ivermectin is the most reasonable explanation for the decrease in morbidity and fatality rate in Africa. In areas where ivermectin is distributed to and used by the entire population, it leads to a significant reduction in mortality."

[1038] ***Exploring the binding efficacy of ivermectin against the key proteins of SARS-CoV-2 pathogenesis: an in silico approach***
Future Virology
Abhigyan Choudhury, Nabarun C. Das, *et al*.
March 25, 2021
https://www.futuremedicine.com/doi/10.2217/fvl-2020-0342

"**Results**: Ivermectin was found as a blocker of viral replicase, protease and human TMPRSS2, which could be the biophysical basis behind its antiviral efficiency. The antiviral action and ADMET profile of ivermectin was on par with the currently used anticorona drugs such as hydroxychloroquine and remdesivir.

Conclusion: Our study enlightens the candidature of ivermectin as an effective drug for treating COVID-19."

[1039] ***The BIRD Recommendation on the Use of Ivermectin for Covid-19***
British Ivermectin Recommendation Development (BIRD) panel
Tess Lawrie, Fahmida Shaik, *et al*.
March 22, 2021
https://bird-group.org/wp-content/uploads/2021/03/BIRD-Proceedings-22-03-2021-final.pdf
Supporters and endorsements: https://bird-group.org/who-are-bird/

"**Executive Summary**: The antiparasitic medicine ivermectin, which is widely available in LMICs [*low- and middle-income countries*], has been tested in numerous clinical trials of prevention and treatment of covid-19 with promising results. A large body of evidence on ivermectin use in covid-19 had thus accumulated, which required urgent review by health professionals and other stakeholders to determine whether it could inform clinical practice in the UK and elsewhere. More specifically, answers were needed to the following priority questions: (i) For people with covid-19 infection, does ivermectin compared with placebo or no ivermectin improve health outcomes?, and (ii) for people at higher risk of covid-19 infection, does ivermectin compared with placebo or no ivermectin improve health outcomes?

On the 20th of February 2021, the British Ivermectin Recommendation Development (BIRD) meeting was convened in Bath, United Kingdom, to evaluate the evidence on ivermectin use for the prevention and treatment of covid-19. Evidence to address the priority questions was evaluated by a panel of clinical experts and other stakeholders in the form of a DECIDE evidence-to-decision framework, the gold standard tool for developing clinical practice guidelines…

The British Ivermectin Recommendation Development panel **recommends ivermectin for the prevention and treatment of covid-19 to reduce morbidity and mortality** associated with covid-19 infection and to prevent covid-19 infection among those at higher risk [*emphasis added*]."

[1040] ***Global trends in clinical studies of ivermectin in COVID-19***
Japanese Journal of Antibiotics
Morimasa Yagiswa, Patricck J. Foster, Hideaki Hanaki, and Satoshi Omura
March 10, 2021
https://covid19criticalcare.com/wp-content/uploads/2021/04/Satoshi-Omura-Global-trends-in-clinical-studies-of-ivermectin-in-COVID-19-Japanese-Journal-of-Antibiotics-March-10-2021.pdf

"This review is written with the hope of increasing the understanding and support of all parties, by explaining the current situation in which doctors and researchers all around the world are actively attempting to expand the indication for ivermectin as a therapeutic/preventive drug for COVID-19. It is hoped that ivermectin will be utilized as a countermeasure for COVID-19 as soon as possible…

Although clinical trial results have been and continue to be accumulated showing that ivermectin is effective in the treatment and prevention of COVID-19, basic in vitro findings that can reasonably explain its effectiveness have not yet been obtained…

When the effectiveness of ivermectin for the COVID-19 pandemic is confirmed with the cooperation of researchers around the world and its clinical use is achieved on a global scale, it could prove to be of great benefit to humanity. It may even turn out to be comparable to the benefits achieved from the discovery of penicillin—said to be one of the greatest discoveries of the twentieth century. Here, one more use for ivermectin, which has been described as 'miracle' or 'wonder' drug, is being added."

[1041] ***Role of ivermectin in the prevention of SARS-CoV-2 infection among healthcare workers in India: A matched case-control study***
PLOS One
Priyamadhaba Behera, Binod Kumar Patro, *et al*.
February 16, 2021
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247163

"**Background**: Ivermectin is one among several potential drugs explored for its therapeutic and preventive role in SARS-CoV-2 infection. The study was aimed to explore the association between ivermectin prophylaxis and the development of SARS-CoV-2 infection among healthcare workers…

Conclusion: Two-dose ivermectin prophylaxis at a dose of 300 µg/kg with a gap of 72 hours was associated with a 73% reduction of SARS-CoV-2 infection among healthcare workers for the following month. Chemoprophylaxis has relevance in the containment of pandemic."

[1042] ***COVID-19 Treatment Guidelines – Ivermectin***
National Institutes of Health (NIH)
Last updated February 11, 2021
https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/

"Reports from *in vitro* studies suggest that ivermectin acts by inhibiting the host importin alpha/beta-1 nuclear transport proteins, which are part of a key intracellular transport process that viruses hijack to enhance infection by suppressing the host's antiviral response. In addition, ivermectin docking may interfere with the attachment of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein to the human cell membrane… Some studies of ivermectin have also reported potential anti-inflammatory properties, which have been postulated to be beneficial in people with COVID-19."

[1043] ***The Use of Compassionate Ivermectin in the Management of Symptomatic Outpatients and Hospitalized Patients with Clinical Diagnosis of Covid-19 at the Centro Medico Bournigal and at the Centro Medico Punta Cana, Grupo Rescue, Dominican Republic, from May 1 to August 10, 2020***
Journal of Clinical Trials
Jose Morgenstern, Jose N. Redondo, *et al*.
February 2, 2021
https://www.longdom.org/open-access/the-use-of-compassionate-ivermectin-in-the-management-of-symptomatic-outpatients-and-hospitalized-patients-with-clinical.pdf

"**Abstract**: … In the present Retrospective observational study, 3,099 patients with a definitive or highly probable diagnosis of infection due to COVID-19 were evaluated… A total of 2,706 (87.3%) were discharged for outpatient treatment, all with mild severity of the infection… In 2,688 (99.33%) with outpatient treatment, **the disease did not progress to warrant further hospitalization** and **there were no deaths** [*emphasis added*]. In 16 (0.59%) with outpatient treatment, it was necessary their subsequent hospitalization to a room without any death. In 2 (0.08%) with outpatient treatment, it was necessary their admission to the Intensive Care Unit (ICU) and 1 (0.04%) patient died. There were 411 (13.3%) patients hospitalized, being admitted at a COVID-19 room with a moderate disease 300 (9.7%) patients of which 3 (1%) died; and with a severe to critical disease were hospitalized in the ICU 111 (3.6%), 34 (30.6%) of whom died. The mortality percentage of patients admitted to the ICU of 30.6% is similar with the percentage found in the literature of 30.9%. Total mortality was 37 (1.2%) patients, which is much lower than that reported in world statistics, which are around 3%, by the time of completion of this study."

[1044] ***Sharp Reductions in COVID-19 Case Fatalities and Excess Deaths in Peru in Close Time Conjunction, State-By-State, with Ivermectin Treatments***
Social Science Research Network (SSRN)
Juan J. Chamie-Quintero, Jennifer Hibberd, and David Scheim
January 12, 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3765018

> "**Abstract**: On May 8, 2020, Peru's Ministry of Health approved ivermectin (IVM) for the treatment of COVID-19. A drug of Nobel Prize-honored distinction, IVM has been safely distributed in 3.7 billion doses worldwide since 1987. It has exhibited major, statistically significant reductions in case mortality and severity in 11 clinical trials for COVID-19, three with randomized controls. The indicated biological mechanism of IVM is the same as that of antiviral antibodies generated by vaccines—binding to SARS-CoV-2 viral spike protein, blocking viral attachment to host cells…
>
> For the 24 states with early IVM treatment (and Lima), **excess deaths dropped 59% (25%) at +30 days and 75% (25%) at +45 days** after day of peak deaths [*emphasis added*]. Case fatalities likewise dropped sharply in all states but Lima, yet six indices of Google-tracked community mobility rose over the same period. For nine states having mass distributions of IVM in a short timeframe through a national program, Mega-Operación Tayta (MOT), excess deaths at +30 days dropped by a population-weighted mean of 74%... Its safety well established even at high doses, IVM is a compelling option for immediate, large scale national deployments as an interim measure and complement to pandemic control through vaccinations."

[1045] ***Ivermectin: an award-winning drug with expected antiviral activity against COVID-19***
Journal of Controlled Release
Fabio Rocha Formiga, Roger Leblanc, *et al*.
January 10, 2021
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7539925/

> "**Abstract**: Ivermectin is an FDA-approved broad-spectrum antiparasitic agent with demonstrated antiviral activity against a number of DNA and RNA viruses, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Despite this promise, the antiviral activity of ivermectin has not been consistently proven in vivo. While ivermectin's activity against SARS-CoV-2 is currently under investigation in patients, insufficient emphasis has been placed on formulation challenges. Here, we discuss challenges surrounding the use of ivermectin in the context of coronavirus disease-19 (COVID-19) and how novel formulations employing micro- and nanotechnologies may address these concerns…"

[1046] ***Meta-analysis of clinical trials of ivermectin to treat COVID-19 infection***
Unitaid & University of Liverpool
Dr. Andrew Hill
December 2020
https://swprs.org/wp-content/uploads/2021/01/andrew_hill_ivermectin_slides_december_2020.pdf

Slide 4: "Search strategy: Systematic review of randomised trials of ivermectin to treat COVID-19 infection"

Slide 5: "Meta-analysis methods: Only the randomised clinical trials were included: in WHO GRADE criteria, systematic review and meta-analysis provides the highest level of evidence"

Slide 23: "Conclusions: In this meta-analysis of 11 randomised trials in 1452 patients, Ivermectin treatment was associated with:

- Faster time to viral clearance
- Shorter duration of hospitalisation
- 43% higher rates of clinical recovery (95% C.I. 21-67%)
- **83% improvement in survival rates** [*emphasis added*] (95% C.I. 65-92%)

[1047] ***Ivermectin as Prophylaxis Against COVID-19 Retrospective Cases Evaluation Microbiology & Infectious Diseases***
Roberto R. Hirsch and Hector E. Carvallo
December 2020
https://scivisionpub.com/pdfs/ivermectin-as-prophylaxis-against-covid19-retrospective-cases-evaluation-1458.pdf

"**Abstract**: … Ivermectin has shown its usefulness against SARS COV2, both in treatment and in prophylaxis.

Therefore, this work compiles the characteristics of the group of Health Agents (and their close contacts) from a Buenos Aires Hospital specialized in Infectious Diseases, who resorted to it, as well as the results that were obtained…

Conclusion: … From the data included in this compilation, it appears that Ivermectin has been an excellent adjuvant method for Personal Protective Equipment, for the prophylaxis of SARS Cov 2 in health personnel and their contacts.

As such, it is not only recommended to extend it to all Health Agents, but also to all vulnerable population groups (geriatric and psychiatric institutes, orphanages, prisons, etc.)."

[1048] ***Ivermectin as Pre-exposure Prophylaxis for COVID-19 among Healthcare Providers in a Selected Tertiary Hospital in Dhaka – An Observational Study***
European Journal of Medical & Health Services
Mohammed Tarek Alam, Rubaiul Murshed, *et al*.
December 15, 2020
https://www.ejmed.org/index.php/ejmed/article/view/599/337

"**Abstract**

Introduction: While multiple vaccines are undergoing clinical trial across the globe, we yearn for an FDA approved drug to protect us from the devastating pandemic for the time being. This study aims to determine the effectiveness of Ivermectin when administered as pre-exposure prophylaxis for COVID-19…

Result: 73.3% (44 out of 60) subjects in control group were positive for COVID-19, whereas only 6.9% (4 out of 58) of the experimental group were diagnosed with COVID-19 (p-value < 0.05).

Conclusion: Ivermectin, an FDA-approved, safe, cheap and widely available drug, should be subjected to large-scale trials all over the world to ascertain its effectiveness as pre-exposure prophylaxis for COVID-19."

[1049] **Video (28m): Sub-committee hearing on early treatment of COVID-19 - Testimony of Pierre Kory, MD**
US Senate
December 8, 2020
https://odysee.com/@FrontlineCovid19CriticalCareAlliance:c/Dr.-Pierre-Kory-FLCCC-Alliance-testifies-to-senate-committee-about-I-MASK-incl.-the-following-QA-part-490351508:3
Transcript: https://www.hsgac.senate.gov/imo/media/doc/Testimony-Kory-2020-12-08.pdf

"I am speaking today not only as an individual physician, but also on behalf of my non-profit organization, the Front-Line COVID-19 Critical Care Alliance, made up of some of the most highly published and well-known critical care experts in the world with almost 2,000 peer - reviewed publications in the medical literature as well as over 100 years of bedside clinical experience in ICU's around the country…

In the last 3-4 months, emerging publications provide conclusive data on the profound efficacy of the anti-parasite, anti-viral drug, anti-inflammatory agent called ivermectin in all stages of the disease. Our protocol was created only recently, after we identified these data. Nearly all studies are demonstrating the therapeutic potency and safety of ivermectin in preventing transmission and progression of illness in nearly all who take the drug...

We now have data from over 20 well-designed clinical studies, ten of them randomized, controlled trials, with **every study consistently reporting large magnitude and statistically significant benefits** in decreasing transmission rates, shortening recovery times, decreasing hospitalizations, or large reductions in deaths. This clinical data is also supported by multiple basic science, in-vitro and animal studies [*emphasis added*]…

It should be noted that Merck, the pharmaceutical company whose scientists helped discover ivermectin, has from the first availability of the drug, donated hundreds of millions of doses for free to support the WHO parasite eradication programs. We believe a similar initiative is needed to eradicate the globe from the scourge of COVID-19."

[1050] ***A COVID-19 prophylaxis? Lower incidence associated with prophylactic administration of ivermectin***
International Journal of Antimicrobial Agents
Martin D. Hellwig and Anabela Maia
November 28, 2020
https://www.sciencedirect.com/science/article/abs/pii/S0924857920304684

"Highlights

- Mass administration of ivermectin is associated with lower COVID-19 incidence.
- Ivermectin has been shown to inhibit SARS-CoV-2 replication in vitro.
- Ivermectin may have a prophylactic effect against COVID-19.
- COVID-19 prophylaxis could help bridge the time until a vaccine becomes widely available.

Abstract: As COVID-19 (coronavirus disease 2019) continues to rapidly spread throughout the world, the incidence varies greatly among different countries… Here, we show that **countries with routine mass drug administration of prophylactic chemotherapy including ivermectin have a significantly lower incidence of COVID-19**. Prophylactic use of ivermectin against parasitic infections is most common in Africa and we hence show that the reported correlation is highly significant both when compared among African nations as well as in a worldwide context. We surmise that this may be connected to ivermectin's ability to inhibit SARS-CoV-2 replication, which likely leads to lower infection rates."

[1051] ***Use of Ivermectin Is Associated With Lower Mortality in Hospitalized Patients With Coronavirus Disease 2019***
Chest Journal
Juliana Cepelowicz Rajter, Michael S. Sherman, *et al*.
October 12, 2020
https://journal.chestnet.org/article/S0012-3692(20)34898-4/fulltext

"**Background**: Ivermectin was shown to inhibit severe acute respiratory syndrome coronavirus 2 replication in vitro, which has led to off-label use, but clinical efficacy has not been described previously…

Results: Two hundred eighty patients, 173 treated with ivermectin and 107 without ivermectin, were reviewed… Univariate analysis showed lower mortality in the ivermectin group… Mortality also was lower among ivermectin-treated patients with severe pulmonary involvement…

Interpretation: Ivermectin treatment was associated with lower mortality during treatment of COVID-19, especially in patients with severe pulmonary involvement. Randomized controlled trials are needed to confirm these findings."

[1052] ***Ivermectin Docks to the SARS-CoV-2 Spike Receptor-binding Domain Attached to ACE2***
In Vivo
Steven Lehrer and Peter H. Rheinstein
August 31, 2020
https://iv.iiarjournals.org/content/34/5/3023

"**Abstract**: Background/Aim: Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). One drug that has attracted interest is the antiparasitic compound ivermectin, a macrocyclic lactone derived from the bacterium Streptomyces avermitilis. We carried out a docking study to determine if ivermectin might be able to attach to the SARS-CoV-2 spike receptor-binding domain bound with ACE2…

Conclusion: The ivermectin docking site we identified, between the viral spike and the ACE2 receptor, may interfere with the attachment of the spike to the human cell membrane. Our observation is consistent with the findings of Caly et al. and Patel et al."

[1053] ***Ivermectin: a systematic review from antiviral effects to COVID-19 complementary regimen***
Journal of Antibiotics
Fatemeh Heidary and Reza Gharebaghi
June 12, 2020
https://www.nature.com/articles/s41429-020-0336-z

"**Abstract**: Ivermectin proposes many potentials effects to treat a range of diseases, with its antimicrobial, antiviral, and anti-cancer properties as a wonder drug. It is highly effective against many microorganisms including some viruses. In this comprehensive systematic review, antiviral effects of ivermectin are summarized including in vitro and in vivo studies over the past 50 years…

Conclusion: In this systematic review, we showed antiviral effects of ivermectin on a broad range of RNA and DNA viruses by reviewing all related evidences since 1970…

Ivermectin, owing to its antiviral activity, may play a pivotal role in several essential biological processes, therefore it could serve as a potential candidate in the treatment of different types of viruses including COVID-19."

[1054] ***The broad spectrum antiviral ivermectin targets the host nuclear transport importin α/β1 heterodimer***
Antiviral Research
Sundy N.Y. Yang, Sarah C. Atkinson, *et al*.
May 2020
https://www.sciencedirect.com/science/article/abs/pii/S0166354219307211

"**Abstract**: … Although RNA viruses replicate in the infected host cell cytoplasm, the nucleus is central to key stages of the infectious cycle of HIV-1 and influenza, and an important target of DENV nonstructural protein 5 (NS5) in limiting the host antiviral response. We previously identified the small molecule ivermectin as an inhibitor of HIV-1 integrase nuclear entry, subsequently showing ivermectin could inhibit DENV NS5 nuclear import, as well as limit infection by viruses such as HIV-1 and DENV. We show here that ivermectin's broad spectrum

antiviral activity relates to its ability to target the host importin (IMP) α/β1 nuclear transport proteins responsible for nuclear entry of cargoes such as integrase and NS5. We establish for the first time that ivermectin can dissociate the preformed IMPα/β1 heterodimer, as well as prevent its formation, through binding to the IMPα armadillo (ARM) repeat domain to impact IMPα thermal stability and α-helicity. We show that ivermectin inhibits NS5-IMPα interaction in a cell context using quantitative bimolecular fluorescence complementation. Finally, we show for the first time that ivermectin can limit infection by the DENV-related West Nile virus at low (μM) concentrations. Since it is FDA approved for parasitic indications, ivermectin merits closer consideration as a broad spectrum antiviral of interest."

[1055] ***The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro***
Antiviral Research
Leon Caly, Julian D. Druce, *et al*.
April 3, 2020
https://www.sciencedirect.com/science/article/pii/S0166354220302011?via%3Dihub

"**Highlights**:

- Ivermectin is an inhibitor of the COVID-19 causative virus (SARS-CoV-2) *in vitro*.
- A single treatment able to effect ~5000-fold reduction in virus at 48 h in cell culture.
- Ivermectin is FDA-approved for parasitic infections, and therefore has a potential for repurposing.
- Ivermectin is widely available, due to its inclusion on the WHO model list of essential medicines.

1. Introduction: Ivermectin is an FDA-approved broad spectrum anti-parasitic agent (Gonzalez Canga et al., 2008) that in recent years we, along with other groups, have shown to have anti-viral activity against a broad range of viruses (Gotz et al., 2016; Lundberg et al., 2013; Tay et al., 2013; Wagstaff et al., 2012) *in vitro*…

Taken together these results demonstrate that **ivermectin has antiviral action against the SARS-CoV-2 clinical isolate *in vitro***, with a single dose able to control viral replication within 24–48 h in our system [*emphasis added*]. We hypothesise that this is likely through inhibiting IMPα/β1-mediated nuclear import of viral proteins (Fig. 1G), as shown for other RNA viruses (Tay et al., 2013; Wagstaff et al., 2012; Yang et al., 2020)... Ultimately, development of an effective anti-viral for SARS-CoV-2, if given to patients early in infection, could help to limit the viral load, prevent severe disease progression and limit person-person transmission…

Ivermectin has an established safety profile for human use [*emphasis added*] (Gonzalez Canga et al., 2008; Jans et al., 2019; Buonfrate et al., 2019), and is FDA-approved for a number of parasitic infections (Gonzalez Canga et al., 2008; Buonfrate et al., 2019). Importantly, recent reviews and meta-analysis indicate that high dose ivermectin has comparable safety as the standard low-dose treatment."

Monoclonal Antibodies

Note: The citations below are presented in reverse, chronological order.

[1056] ***Potent neutralization of SARS-CoV-2 variants of concern by an antibody with an uncommon genetic signature and structural mode of spike recognition***
Cell Reports (Vanderbilt University Medical Center)
Kevin J. Kramer, Nicole V. Johnson, *et al*.
October 5, 2021
https://www.cell.com/cell-reports/fulltext/S2211-1247(21)01243-2

> "**Summary**: … Here, we report a panel of SARS-CoV-2 antibodies isolated using the linking B cell receptor to antigen specificity through sequencing (LIBRA-seq) technology from an individual who recovered from COVID-19. Of these antibodies, 54042-4 shows **potent neutralization** against authentic SARS-CoV-2 viruses, including variants of concern (VOCs). A cryoelectron microscopy (cryo-EM) structure of 54042-4 in complex with the SARS-CoV-2 spike reveals an epitope composed of residues that are highly conserved in currently circulating SARS-CoV-2 lineages. Further, 54042-4 possesses uncommon genetic and structural characteristics that distinguish it from other potently neutralizing SARS-CoV-2 antibodies. Together, these findings provide motivation for the development of 54042-4 as a **lead candidate to counteract current** and f**uture SARS-CoV-2 VOCs** [*emphasis added*]."

[1057] ***Monoclonal Antibodies vs. Vaccines vs. COVID-19: What to Know***
WebMD Health News
Donavyn Coffey
August 26, 2021
https://www.webmd.com/vaccines/covid-19-vaccine/news/20210826/monoclonal-antibodies-vs-vaccines-vs-covid-19

> "Clinical trials show that Regeneron's monoclonal antibody treatment, a combination of two antibodies called casirivimab and imdevimab, **reduces COVID-19-related hospitalization or deaths in high-risk patients by about 70%** [*emphasis added*]. And when given to an exposed person -- like someone living with an infected person -- monoclonal antibodies reduced their risk of developing an infection with symptoms by 80%."

[1058] ***COVID-19 Treatment Guidelines - Anti-SARS-CoV-2 Monoclonal Antibodies***
National Institutes of Health (NIH)
Updated August 4, 2021
https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/

> "Monoclonal antibodies that target the spike protein have been shown to have a **clinical benefit in treating SARS-CoV-2 infection** [*emphasis added*] (as discussed below). Preliminary data suggest that monoclonal antibodies may play a role in preventing SARS-CoV-2 infection in household contacts of infected patients and during skilled nursing and assisted living facility outbreaks."

[1059] ***Impact of Bamlanivimab Monoclonal Antibody Treatment on Hospitalization and Mortality Among Nonhospitalized Adults With Severe Acute Respiratory Syndrome Coronavirus 2 Infection***
Open Forum Infectious Diseases
J. Ryan Bariola, Erin K. McCreary, *et al*.
May 17, 2021
https://academic.oup.com/ofid/article/8/7/ofab254/6276906

"**Results**: … After adjustment for propensity to receive treatment, bamlanivimab treatment was associated with a significantly reduced risk-adjusted odds of hospitalization or mortality within 28 days (odds ratio [OR], 0.40; 95% confidence interval [95% CI], 0.24–0.69; P < .001). Bamlanivimab treatment was also associated with a significantly lower risk adjusted odds of hospitalization or emergency department visit without hospitalization (OR, 0.54; 95% CI, 0.35–0.82; P = .004). The results were most strongly associated with patients age 65 years and older.

Conclusions: Bamlanivimab monoclonal antibody monotherapy was associated with reduced hospitalizations and mortality within 28 days among outpatients with mild to moderate COVID-19.

Use of bamlanivimab monotherapy for outpatients with mild to moderate COVID-19 infection was associated with reductions in hospitalizations and mortality within 28 days. Benefit was strongest in those age 65 years or older."

[1060] ***Cross-neutralization of SARS-CoV-2 by a human monoclonal SARS-CoV antibody***
Nature magazine
Dora Pinto, Young-Jun Park, *et al*.
May 18, 2020
https://www.nature.com/articles/s41586-020-2349-y

"**Abstract**: … The SARS-CoV-2 spike (S) glycoprotein promotes entry into host cells and is the main target of neutralizing antibodies. Here we describe **several monoclonal antibodies that target the S glycoprotein of SARS-CoV-2**, which we identified from memory B cells of an individual who was infected with severe acute respiratory syndrome coronavirus (SARS-CoV) in 2003. One antibody (named S309) potently neutralizes SARS-CoV-2 and SARS-CoV pseudoviruses as well as authentic SARS-CoV-2, by engaging the receptor-binding domain of the S glycoprotein. Using cryo-electron microscopy and binding assays, we show that S309 recognizes an epitope containing a glycan that is conserved within the Sarbecovirus subgenus, without competing with receptor attachment. Antibody cocktails that include S309 in combination with other antibodies that we identified further enhanced SARS-CoV-2 neutralization, and may limit the emergence of neutralization-escape mutants. **These results pave the way for using S309 and antibody cocktails containing S309 for prophylaxis in individuals at a high risk of exposure** or as a post-exposure therapy to limit or treat severe disease [*emphasis added*]."

[1061] ***Effective treatment of severe COVID-19 patients with tocilizumab***
Proceedings of the National Academy of Sciences (PNAS)
Xiaoling Xu, Mingfeng Han, *et al*.
April 29, 2020
https://www.pnas.org/content/117/20/10970

> "**Significance**: In patients with coronavirus disease 2019, a large number of T lymphocytes and mononuclear macrophages are activated, producing cytokines such as interleukin-6 (IL-6), which bind to the IL-6 receptor on the target cells, causing the cytokine storm and severe inflammatory responses in lungs and other tissues and organs. Tocilizumab, as a recombinant humanized anti-human IL-6 receptor monoclonal antibody, can bind to the IL-6 receptor with high affinity, thus preventing IL-6 itself from binding to its receptor, rendering it incapable of immune damage to target cells, and alleviating the inflammatory responses."

Povidone-iodine

Note: The citations below are presented in reverse, chronological order.

[1062] **ADDED since 2/8/2008**
Effect of 1% Povidone Iodine Mouthwash/Gargle, Nasal and Eye Drop in COVID-19 patient
Bangladesn Journals Online — Bioresearch Communications
Md Iqbal Mahmud Choudhury, Nilufar Shabnam, *et al*.
June 23, 2021
https://www.banglajol.info/index.php/BRC/article/view/54245/37954

> "**Background**:… Povidone iodine (PVP-I) is an antiseptic that has been used for over 150 years. It is already proved that different concentration of PVP-I can deactivate COVID-19 virus.
>
> **Methodology**: In this randomized controlled clinical trial,out of 1113 patients, 606 patients were enrolled and divided in 2 groups by randomization after taken consents. In Gr-A, 303 patients underwent mouthwash/gargle, nasal drops and eye drops with 1% povidone iodine 4 hourly for 4 weeks as well as symptomatic treatment according to need. In Gr-B, 303 patients were advised mouthwash/gargle, nasal cavity and eye wash with lukewarm water 4 hourly for 4 weeks and symptomatic treatment according to need…
>
> **Results**: … In group A (patients used PVP-I), only **2.64%** (N-8) patient is RT-PCR positive on the 7th day, whereas in group B (patients used lukewarm water), it is 70.30% (N-213) (Table 2, Gr- A & B) (p>0.05). Data of Table 3 (Gr-A&B) shows that 3.30% (N-10) hospitalized patients of group A needed oxygen support (by mechanical ventilatorand/or high flow nasal cannula and/or non rebreather mask and/or face mask and/or nasal cannula) but 20.79% (N-63) patients of group B needed oxygen support. **Mortality rate** is high[*er*] 5.6% (N-17) in group B than 0.66% (N-2) in group A. The differences were statistically significant (P<0.05)."

[1063] ***Differential Effects of Antiseptic Mouth Rinses on SARS-CoV-2 Infectivity In Vitro Pathogens***
Chuan Xu, Annie Wang, *et al*.
March 1, 2021
https://www.mdpi.com/2076-0817/10/3/272

"**Abstract**: … [W]e determined the effect of commercially available mouth rinses and antiseptic povidone-iodine on the infectivity of replication-competent SARS-CoV-2 viruses and of pseudotyped SARS-CoV-2 viruses. We first determined the effect of mouth rinses on cell viability to ensure that antiviral activity was not a consequence of mouth rinse-induced cytotoxicity. Colgate Peroxyl (hydrogen peroxide) exhibited the most cytotoxicity, followed by povidone-iodine, chlorhexidine gluconate (CHG), and Listerine (essential oils and alcohol)… Mouth rinses inactivated the virus without prolonged incubation. The new infectivity assay, with limited impacts of mouth rinse-associated cytotoxicity, showed the differential effects of mouth rinses on SARS-CoV-2 infection. Our results indicate that mouth rinses can significantly reduce virus infectivity, suggesting a potential benefit for reducing SARS-CoV-2 spread."

Other Conventional Medicine

Note: The citations below are presented in reverse, chronological order.

[1064] **ADDED since 2/8/2008**
Prevalence and Mechanisms of Mucus Accumulation in COVID-19 Lung Disease
American Journal of Respiratory and Critical Care Medicine — Marsico Lung Institute
Takafumi Kato, Takanori Asakura, *et al*.
November 22, 2021
https://www.atsjournals.org/doi/10.1164/rccm.202111-2606OC

"**Conclusions**: SARS-CoV-2 infection is associated with a high prevalence of distal airspace mucus accumulation and increased MUC5B expression in COVID-19 autopsy lungs. HBE culture studies identified roles for EGFR and IL-1R signaling in mucin gene regulation after SARS-CoV-2 infection. These data suggest that time-sensitive **mucolytic agents**, **specific pathway inhibitors**, or **corticosteroid administration** may be therapeutic for COVID-19 lung disease."

[1065] ***Heparin Inhibits Cellular Invasion by SARS-CoV-2: Structural Dependence of the Interaction of the Spike S1 Receptor-Binding Domain with Heparin***
Thrombosis and Haemostasis
Courtney J. Mycroft-West, Dunhao Su, *et al*.
December 23, 2020
https://www.thieme-connect.de/products/ejournals/html/10.1055/s-0040-1721319

"**Abstract**: … Exogenous heparin prevents infection by a range of viruses, including S-associated coronavirus isolate HSR1. Here, we show that heparin inhibits severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) invasion of Vero cells by up to 80% at doses achievable through prophylaxis and, particularly relevant, within the range deliverable by nebulisation. Surface plasmon resonance and circular dichroism spectroscopy

demonstrate that heparin and enoxaparin, a low-molecular-weight heparin which is a clinical anticoagulant, bind and induce a conformational change in the spike (S1) protein receptor-binding domain (S1 RBD) of SARS-CoV-2… The results suggest a route for the rapid development of a first-line therapeutic by repurposing heparin and its derivatives as antiviral agents against SARS-CoV-2 and other members of the Coronaviridae."

[1066] ***N-Acetylcysteine to Combat COVID-19: An Evidence Review***
Therapeutics and Clinical Risk Management
Zhongcheng Shi and Carlos A Puyo
November 2, 2020
https://www.dovepress.com/n-acetylcysteine-to-combat-covid-19-an-evidence-review-peer-reviewed-fulltext-article-TCRM

"**Abstract**: … N-acetylcysteine (NAC) has been used in clinical practice to treat critically ill septic patients, and more recently for COVID-19 patients. NAC has antioxidant, anti-inflammatory and immune-modulating characteristics that may prove beneficial in the treatment and prevention of SARS-Cov-2. This review offers a thorough analysis of NAC and discusses its potential use for treatment of COVID-19."

[1067] ***In Vitro Antiviral Activity of Doxycycline against SARS-CoV-2***
Molecules
Mathieu Gendrot, Julien Andreani, *et al*.
October 31, 2020
https://www.mdpi.com/1420-3049/25/21/5064/htm

"**Abstract**: … Doxycycline, which is a second-generation tetracycline with broad-spectrum antimicrobial, antimalarial and anti-inflammatory activities, showed in vitro activity on Vero E6 cells infected with a clinically isolated SARS-CoV-2 strain (IHUMI-3) with median effective concentration (EC50) of 4.5 ± 2.9 µM, compatible with oral uptake and intravenous administrations. Doxycycline interacted both on SARS-CoV-2 entry and in replication after virus entry. Besides its in vitro antiviral activity against SARS-CoV-2, doxycycline has anti-inflammatory effects by decreasing the expression of various pro-inflammatory cytokines and could prevent co-infections and superinfections due to broad-spectrum antimicrobial activity. Therefore, doxycycline could be a potential partner of COVID-19 therapies."

[1068] ***Anakinra for severe forms of COVID-19: a cohort study***
The Lancet
Thomas Huet, Helene Beaussier, *et al*.
May 29, 2020
https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(20)30164-8/fulltext

"**Background**: … It has been postulated that anakinra, a recombinant IL-1 receptor antagonist, might help to neutralise the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-related hyperinflammatory state, which is considered to be one cause of acute respiratory distress among patients with COVID-19. We aimed to assess the off-label use of anakinra in patients who were admitted to hospital for severe forms of COVID-19 with symptoms indicative of worsening respiratory function…

Interpretation: Anakinra reduced both need for invasive mechanical ventilation in the ICU and mortality among patients with severe forms of COVID-19, without serious side-effects. Confirmation of efficacy will require controlled trials."

[1069] ***Transplantation of ACE2- Mesenchymal Stem Cells Improves the Outcome of Patients with COVID-19 Pneumonia***
Aging and Disease
Zikuan Leng, Rongjia Zhu, *et al*.
April 2020
http://www.aginganddisease.org/EN/10.14336/AD.2020.0228

"**Abstract**: A coronavirus (HCoV-19) has caused the novel coronavirus disease (COVID-19) outbreak in Wuhan, China. Preventing and reversing the cytokine storm may be the key to save the patients with severe COVID-19 pneumonia. Mesenchymal stem cells (MSCs) have been shown to possess a comprehensive powerful immunomodulatory function. This study aims to investigate whether MSC transplantation improves the outcome… [T]he intravenous transplantation of MSCs was safe and effective for treatment in patients with COVID-19 pneumonia, especially for the patients in critically severe condition."

[1070] **Letter: *A retrospective cohort study of methylprednisolone therapy in severe patients with COVID-19 pneumonia***
Signal Transduction and Targeted Therapy (Nature)
Yin Wang, Weiwei Jiang, *et al*.
April 28, 2020
https://www.nature.com/articles/s41392-020-0158-2

"Aggravation of symptoms always occurs during 5–7 days after onset in patients with COVID-19 pneumonia and severe cases develop rapidly to acute respiratory failure. Therefore, it is important to strengthen the treatment to suppress the pro-inflammatory response and control the cytokine storm at this stage. Methylprednisolone are the classical immunosuppressive drugs, which are important to stop or delay the progress of the pneumonia, and have been proved to be effective for the treatment of acute respiratory distress syndrome (ARDS) [*acute respiratory distress syndrome*]…

In conclusion, early, low-dose and short-term application of methylprednisolone was associated with better clinical outcomes in severe patients with COVID-19 pneumonia, and should be considered before the occurrence of ARDS."

[1071] ***SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor***
Cell
Markus Hoffmann, Hanna Kleine-Weber, *et al*.
March 5, 2020
https://www.cell.com/cell/fulltext/S0092-8674(20)30229-4

"**Summary**: … Cell entry of coronaviruses depends on binding of the viral spike (S) proteins to cellular receptors and on S protein priming by host cell proteases. Unravelling which cellular factors are used by SARS-CoV-2 for entry might provide insights into viral transmission and reveal therapeutic targets. Here, we demonstrate that SARS-CoV-2 uses the SARS-CoV

receptor ACE2 for entry and the serine protease TMPRSS2 for S protein priming. A TMPRSS2 inhibitor approved for clinical use blocked entry and might constitute a treatment option. Finally, we show that the sera from convalescent SARS patients cross-neutralized SARS-2-S-driven entry. Our results reveal important commonalities between SARS-CoV-2 and SARS-CoV infection and identify a potential target for antiviral intervention."

Conventional 'Treatments' with Evidence of Harm

Remdesivir

[1072] ***Information for Clinicians on Investigational Therapeutics for Patients with COVID-19***
Centers for Disease Control and Prevention (CDC)
Updated December 8, 2020
https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html

"FDA has approved one drug, remdesivir (Veklury), for the treatment of COVID-19 in hospitalized patients aged 12 years and older who weigh at least 40 kg."

[1073] ***COVID-19 Treatment Guidelines: Table 2e. Characteristics of Antiviral Agents That Are Approved or Under Evaluation for the Treatment of COVID-19***
National Institutes of Health (NIH)
Updated July 8, 2021
https://www.covid19treatmentguidelines.nih.gov/tables/table-2e/

From Table 2e: **Dosing Regimens** for **Remdesivir** for Hospitalized Adults and Children (Aged ≥12 Years and Weighing ≥40 kg):

"The doses and indications listed below come from the FDA product information…

For Patients Who Are Not Mechanically Ventilated and/or on ECMO:

- RDV 200 mg IVa on Day 1, then RDV 100 mg IV on Days 2–5
- For patients who do not show clinical improvement after 5 days of therapy, treatment may be extended to up to 10 days.

For Mechanically Ventilated Patients and/or Patients on ECMO:

- RDV 200 mg IVa on Day 1, then RDV 100 mg IV on Days 2–10
- Adverse Events. Generally well tolerated"

[1074] ***A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics***
New England Journal of Medicine (National Institute of Allergy and Infectious Diseases, US, and Institut National de Recherche Biomédicale, Democratic Republic of Congo)
Sabue Mulangu, Lori E. Dodd, *et al*.
December 12, 2019
https://www.nejm.org/doi/full/10.1056/NEJMoa1910993

"**Background**: Although several experimental therapeutics for Ebola virus disease (EVD) have been developed, the safety and efficacy of the most promising therapies need to be assessed in the context of a randomized, controlled trial.

Methods: We conducted a trial of four investigational therapies for EVD in the Democratic Republic of Congo, where an outbreak began in August 2018. Patients of any age who had a positive result for Ebola virus RNA on reverse-transcriptase–polymerase-chain-reaction assay were enrolled. All patients received standard care and were randomly assigned in a 1:1:1:1 ratio to intravenous administration of the triple monoclonal antibody ZMapp (the control group), the antiviral agent remdesivir, the single monoclonal antibody MAb114, or the triple monoclonal antibody REGN-EB3…

Results: A total of 681 patients were enrolled from November 20, 2018, to August 9, 2019, at which time the data and safety monitoring board recommended that patients be assigned only to the MAb114 and REGN-EB3 groups for the remainder of the trial; the recommendation was based on the results of an interim analysis that showed superiority of these groups to ZMapp and remdesivir **with respect to mortality** [*emphasis added*]…

Trial Procedures: … Patients in the remdesivir group received a loading dose on day 1 (200 mg in adults, and adjusted for body weight in pediatric patients), followed by a daily maintenance dose (100 mg in adults) starting on day 2 and continuing for 9 to 13 days, depending on viral load…"

Note: For comparison, the standard, FDA-recommended dosing regimen of remdesivir for treatment of COVID-19 for hospitalized adults and children is as follows (see [1073]):

- RDV 200 mg IVa on Day 1, then RDV 100 mg IV on Days 2–5
- For patients who do not show clinical improvement after 5 days of therapy, treatment may be extended to up to 10 days.

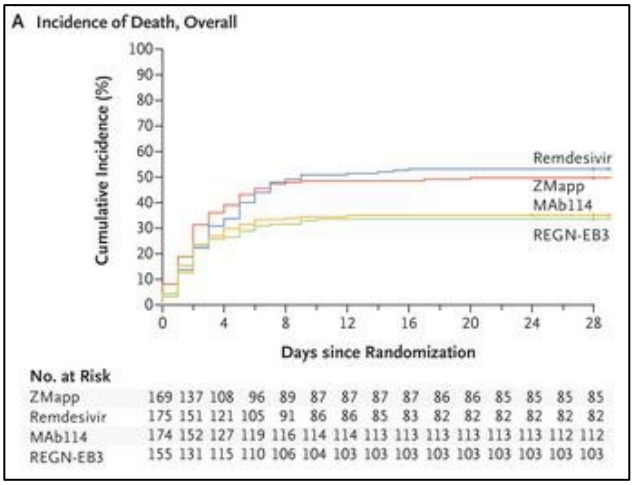
From **Table 2. Comparison of Death at 28 Days According to Treatment Group** (see image below):

- **53.1%** of all remdesivir patients died (93/175)
- **85.3%** of remdesivir patients with high viral load died (64/75)
- 29.0% of remdesivir patients with low viral load died (29/100)

Table 2. Comparison of Death at 28 Days According to Treatment Group.

Population	ZMapp	Remdesivir	Difference, Remdesivir vs. ZMapp	MAb114	Difference, MAb114 vs. ZMapp	REGN-EB3	ZMapp Subgroup	Difference, REGN-EB3 vs. ZMapp Subgroup
	no. of deaths/ total no. (%)	*no. of deaths/ total no. (%)*	*percentage points (95% CI)*	*no. of deaths/ total no. (%)*	*percentage points (95% CI)*	*no. of deaths/ total no. (%)*	*no. of deaths/ total no. (%)*	*percentage points (95% CI)*
Overall	84/169 (49.7)	93/175 (53.1)	3.4 (−7.2 to 14.0)	61/174 (35.1)	−14.6 (−25.2 to −1.7)*	52/155 (33.5)	79/154 (51.3)	−17.8 (−28.9 to −2.9)*
Patients with high viral load†	60/71 (84.5)	64/75 (85.3)	0.8 (−15.3 to 17.2)	51/73 (69.9)	−14.6 (−33.0 to −0.5)	42/66 (63.6)	56/65 (86.2)	−22.5 (−41.8 to −5.1)
Patients with low viral load†	24/98 (24.5)	29/100 (29.0)	4.5 (−9.1 to 19.1)	10/101 (9.9)	−14.6 (−32.4 to −2.6)	10/89 (11.2)	23/89 (25.8)	−14.6 (−32.6 to −2.3)

* The result is significant according to the interim stopping boundary of P<0.035 for the MAb114 group and P<0.028 for the REGN-EB3 group.
† Patients with a high viral load had an EBOV nucleoprotein Ct value of 22.0 or less. Patients with a low viral load had an EBOV nucleoprotein Ct value of more than 22.0. The total number is the total number of patients in this category for each group.



[1075] ***Ebola outbreak treatment trial narrowed to two promising drugs***
Center for Infectious Disease Research and Policy
Lisa Schmining
August 12, 2019
https://www.cidrap.umn.edu/news-perspective/2019/08/ebola-outbreak-treatment-trial-narrowed-two-promising-drugs

> "An independent monitoring board meets periodically to review safety and efficacy data, and at their Aug 9 review recommended that the study (see 0) be stopped and all future patients be randomized to receive either Regeneron, an antibody cocktail, or mAB 114, an antibody treatment developed from a human survivor of the virus. The other two drugs involved in the original trial were zMapp, which in an earlier trial didn't show statistically significant efficacy but performed better than standard care alone, and Remdesivir, an antiviral drug…
>
> At a media telebriefing today, Anthony Fauci, MD, director of the National institute of Allergy and Infectious Diseases (NIAID), said Regeneron was the drug that crossed the efficacy threshold, triggering a pause in the study. And he said the group recommended proceeding with mAb 114, because there were only small differences in the data between the two drugs…
>
> As of Aug 9, the trial had enrolled 681 patients toward a total of 725. Fauci said mortality for Regeneron was 29% and 34% for mAb 114. However, mortality was somewhat higher for zMapp (49%) and Remdesivir (53%). He said results were even more impressive in patients who had low viral loads: 6% for Regeneron, 11% for mAb 114, 24% for zMapp, and 33% for Remdesivir."

[1076] ***Remdesivir and Acute Renal Failure: A Potential Safety Signal From Disproportionality Analysis of the WHO Safety Database***
Clinical Pharmacology & Therapeutics (Universitaire de Nice, France)
Alexandre O. Gerard, Audrey Laurain, *et al*.
December 19, 2020
https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.2145

"**Abstract**: Remdesivir is approved for emergency use by the US Food and Drug Administration (FDA) and authorized conditionally by the European Medicines Agency (EMA) for patients with coronavirus disease 2019 (COVID-19). Its benefit-risk ratio is still being explored because data in the field are rather scant. A decrease of the creatinine clearance associated with remdesivir has been inconstantly reported in clinical trials with unclear relevance. Despite these uncertainties, we searched for a potential signal of acute renal failure (ARF) in pharmacovigilance postmarketing data. An analysis of the international pharmacovigilance postmarketing databases (VigiBase) of the World Health Organization (WHO) was performed, using two disproportionality methods. Reporting odds ratio (ROR) compared the number of ARF cases reported with remdesivir, with those reported with other drugs prescribed in comparable situations of COVID-19 (hydroxychloroquine, tocilizumab, and lopinavir/ritonavir). The combination of the terms 'acute renal failure' and 'remdesivir' yielded a statistically significant disproportionality signal with 138 observed cases instead of the 9 expected. **ROR of ARF with remdesivir was 20-fold** (20.3; confidence interval 0.95 [15.7–26.3], P < 0.0001]) that of comparative drugs. Based on ARF cases reported in VigiBase, and despite the caveats inherent to COVID-19 circumstances, we detected a **statistically significant pharmacovigilance signal of nephrotoxicity associated with remdesivir**, deserving a thorough qualitative assessment of all available data [*emphasis added*]. Meanwhile, as recommended in its Summary of Product Characteristics, assessment of patients with COVID-19 renal function should prevail before and during treatment with remdesivir in COVID-19."

[1077] ***Compassionate Use of Remdesivir for Patients with Severe Covid-19***
Gilead Sciences
Jonathan Grein, Norio Ohmagari, *et al*.
April 10, 2020
https://www.nejm.org/doi/full/10.1056/NEJMoa2007016

"**Methods**: We provided remdesivir on a compassionate-use basis to patients hospitalized with Covid-19, the illness caused by infection with SARS-CoV-2. Patients were those with confirmed SARS-CoV-2 infection who had an oxygen saturation of 94% or less while they were breathing ambient air or who were receiving oxygen support. Patients received a 10-day course of remdesivir, consisting of 200 mg administered intravenously on day 1, followed by 100 mg daily for the remaining 9 days of treatment. This report is based on data from patients who received remdesivir during the period from January 25, 2020, through March 7, 2020, and have clinical data for at least 1 subsequent day…

Mortality: **Seven of the 53 patients (13%) died** after the completion of remdesivir treatment [*emphasis added*], including 6 of 34 patients (18%) who were receiving invasive ventilation and 1 of 19 (5%) who were receiving noninvasive oxygen support…

Safety: A total of 32 patients (60%) reported adverse events during follow-up (Table 2). The most common adverse events were increased hepatic enzymes, diarrhea, rash, renal impairment, and hypotension. In general, adverse events were more common in patients receiving invasive ventilation. A total of **12 patients (23%) had serious adverse events**. The most common serious adverse events — multiple-organ-dysfunction syndrome, septic shock, acute kidney injury, and hypotension [*emphasis added*] — were reported in patients who were receiving invasive ventilation at baseline.

Four patients (8%) discontinued remdesivir treatment prematurely: one because of worsening of preexisting renal failure, one because of multiple organ failure [*emphasis added*], and two because of elevated aminotransferases, including one patient with a maculopapular rash."

Table 2. Summary of Adverse Events.

Event	Invasive Ventilation (N=34)	Noninvasive Oxygen Support (N=19)	Total (N=53)
	number of patients (percent)		
Any adverse event	22 (65)	10 (53)	32 (60)
Adverse events occurring in 2 or more patients			
Hepatic enzyme increased*	8 (24)	4 (21)	12 (23)
Diarrhea	1 (3)	4 (21)	5 (9)
Rash	3 (9)	1 (5)	4 (8)
Renal impairment	4 (12)	0	4 (8)
Hypotension	3 (9)	1 (5)	4 (8)
Acute kidney injury	2 (6)	1 (5)	3 (6)
Atrial fibrillation	2 (6)	1 (5)	3 (6)
Multiple-organ-dysfunction syndrome	3 (9)	0	3 (6)
Hypernatremia	3 (9)	0	3 (6)
Deep-vein thrombosis	3 (9)	0	3 (6)
Acute respiratory distress syndrome	1 (3)	1 (5)	2 (4)
Pneumothorax	2 (6)	0	2 (4)
Hematuria	2 (6)	0	2 (4)
Delirium	1 (3)	1 (5)	2 (4)
Septic shock	2 (6)	0	2 (4)
Pyrexia	1 (3)	1 (5)	2 (4)
Any serious adverse event	9 (26)	3 (16)	12 (23)
Serious events occurring in 2 or more patients			
Multiple-organ-dysfunction syndrome	2 (6)	0	2 (4)
Septic shock	2 (6)	0	2 (4)
Acute kidney injury	2 (6)	0	2 (4)
Hypotension	2 (6)	0	2 (4)

* Adverse-event terms are based on the *Medical Dictionary for Regulatory Activities*, version 22.1. Hepatic enzyme increased includes the following terms: hepatic enzyme increased, alanine aminotransferase increased, aspartate aminotransferase increased, and transaminases increased. Elevated hepatic enzymes resulted in discontinuation of remdesivir therapy in 2 patients.

Note: The citations below are presented in reverse, chronological order.

[1078] **News release: *FDA Approves First Treatment for COVID-19***
Food and Drug Administration (FDA)
October 22, 2020
https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19

> "Today, the U.S. Food and Drug Administration approved the antiviral drug Veklury (remdesivir) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. Veklury is the first treatment for COVID-19 to receive FDA approval."

[1079] ***A living WHO guideline on drugs for covid-19***
British Medical Journal
September 4, 2020
https://www.bmj.com/content/370/bmj.m3379

> WHO recommendations:
>
> "Remdesivir: Recommendation against (weak)…
>
> Patients with covid-19 at any severity: We suggest no remdesivir"

[1080] ***Case report study of the first five COVID-19 patients treated with remdesivir in France***
International Journal of Infectious Diseases (Bichat-Claude Bernard University Hospital and the University of Paris, France)
Marie Dubert, Benoit Visseaux, *et al*.
June 30, 2020
https://www.sciencedirect.com/science/article/pii/S1201971220305282

> "**Discussion**: Of this case series of five COVID-19 patients requiring ICU treatment for respiratory distress and treated with remdesivir, three (patients 1, 3, and 4) had a favourable outcome despite the initial respiratory severity. They were weaned off oxygen between day 14 and day 19 of illness and were discharged between day 20 and day 26 of illness. **Patients 2 and 5 died in the ICU** on day 25 and day 31 of illness with multi-organ failure [*emphasis added*]…
>
> As described in previous case reports (Grein et al., 2020, Kujawski et al., 2020), four of the five patients experienced major side effects while on remdesivir treatment: **two suffered acute renal injury** and two had a maculopapular rash with cytolytic hepatitis [*emphasis added*]. Both kidney failure events could have been related either to remdesivir or to the SARS-CoV-2 infection… A recent randomized controlled study (Wang et al., 2020b) did not show any clinical of benefit for remdesivir treatment, but probably lacked power. Of note, 12% of patients in the remdesivir group discontinued remdesivir due to adverse events (compared with 5% in the placebo group).
>
> In conclusion, the cases of the five patients presented herein highlight some difficulties with remdesivir infusion when administered in most patients with advanced disease. Particular attention should be paid to hepatic and kidney function when administering this treatment."

[1081] **ADDED since 2/8/2022**

Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial

The Lancet

Yeming Wang, Dingyu Zhang, *et al.*

April 29, 2020

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31022-9/fulltext

"**Findings**: Between Feb 6, 2020, and March 12, 2020, 237 patients were enrolled and randomly assigned to a treatment group (158 to remdesivir and 79 to placebo); one patient in the placebo group who withdrew after randomisation was not included in the ITT population. Remdesivir use was not associated with a difference in time to clinical improvement (hazard ratio 1·23 [95% CI 0·87–1·75]). Although not statistically significant, patients receiving remdesivir had a numerically faster time to clinical improvement than those receiving placebo among patients with symptom duration of 10 days or less (hazard ratio 1·52 [0·95–2·43]). Adverse events were reported in 102 (66%) of 155 remdesivir recipients versus 50 (64%) of 78 placebo recipients. **Remdesivir was stopped early because of adverse events** in 18 (12%) patients versus four (5%) patients who stopped placebo early.

Interpretation: In this study of adult patients admitted to hospital for severe COVID-19, remdesivir was **not associated** with statistically significant clinical benefits. However, the numerical reduction in time to clinical improvement in those treated earlier requires confirmation in larger studies."

Ventilators

[1082] ***Observational Study on 255 Mechanically Ventilated Covid Patients at the Beginning of the USA Pandemic***
Smith Center for Infectious Diseases and Urban Health
Leon G. Smith, Nicolas Mendoza, David Dobesh, and Stephen M. Smith
May 31, 2021
https://www.medrxiv.org/content/10.1101/2021.05.28.21258012v1.full-text

> "**Introduction**: This observational study looked at 255 COVID19 patients who required invasive mechanical ventilation (IMV) during the first two months of the US pandemic…
>
> **Results**: By discharge or Day 90, **78.2%** of the cohort expired. The most common pre-existing conditions were hypertension, (63.5%), diabetes (59.2%) and obesity (50.4%)… Causal modeling establishes that weight-adjusted **HCQ and AZM therapy improves survival by over 100%** [*emphasis added*]."

[1083] ***Some doctors moving away from ventilators for virus patients***
AP News
Mike Stobbe
April 8, 2020
https://apnews.com/article/health-us-news-ap-top-news-international-news-virus-outbreak-8ccd325c2be9bf454c2128dcb7bd616d

> "As health officials around the world push to get more ventilators to treat coronavirus patients, some doctors are moving away from using the breathing machines when they can.
>
> The reason: Some hospitals have reported unusually high death rates for coronavirus patients on ventilators, and some doctors worry that the machines could be harming certain patients…
>
> Generally speaking, 40% to 50% of patients with severe respiratory distress die while on ventilators, experts say. But **80% or more of coronavirus patients placed on the machines in New York City have died**, state and city officials say [*emphasis added*].
>
> Higher-than-normal death rates also have been reported elsewhere in the U.S., said Dr. Albert Rizzo, the American Lung Association's chief medical officer.
>
> Similar reports have emerged from China and the United Kingdom. One U.K. report put the figure at 66%. A very small study in Wuhan, the Chinese city where the disease first emerged, said 86% died."

Miscellaneous

Origin of COVID-19

Note: The citations below are presented in reverse, chronological order.

[1084] **ADDED since 2/8/2022**
'BIGGEST COVER-UP IN HISTORY' I worked with the Wuhan lab – I tried to warn them & I KNOW Covid was a lab leak
The Sun
Imogen Braddick
December 3, 2022
https://www.thesun.co.uk/news/20543847/wuhan-lab-warning-covid-lab-leak/

> "Dr Andrew Huff, former vice president of EcoHealth Alliance, claims to have had a ringside seat to what he brands one of the greatest cover-ups in history - and the 'biggest US intelligence failure since 9/11.'
>
> In his new book - *The Truth About Wuhan* - whistleblower Dr Huff claims the pandemic was the result of the US government's funding of dangerous genetic engineering of coronaviruses in China…
>
> Dr Huff, who worked at EcoHealth Alliance from 2014 to 2016 and served as vice president from 2015, worked on the classified side of the research programme as a US government scientist.
>
> The army veteran, from Michigan, said the organisation taught the Wuhan lab the 'best existing methods to engineer bat coronaviruses to attack other species' for many years.
>
> And he claimed 'China knew from day one that this was a genetically engineered agent'.
>
> 'The US government is to blame for the transfer of dangerous biotechnology to the Chinese,' he said…
>
> 'The shocking part of all of this is how the United States government lied to all of us.' …
>
> 'EcoHealth Alliance developed SARS-CoV-2 and was responsible for the development of the agent SARS-CoV-2 during my employment at the organisation,' he said."

[1085] **ADDED since 2/8/2022**
Interim Report: An Analysis of the Origins of the COVID-19 Pandemic
US Senate Committee on Health Education, Labor and Pensions
October 2022
https://www.help.senate.gov/imo/media/doc/report_an_analysis_of_the_origins_of_covid-19_102722.pdf

> "**Section II: Analysis of Research-Related Incident Hypothesis**
>
> Research-related incidents at labs in China, the United States, and elsewhere have happened and, in some instances, resulted in limited human-to-human transmission. For example, there

have been at least six research related incidents involving the escape of SARS-CoV from high-containment laboratories in China (four), Taiwan (one), and Singapore (one)…

In short, human errors, mechanical failure, animal bites, animal escapes, inadequate training, insufficient funding, and pressure for results can lead to an escape of virulent pathogens, which could, in turn, infect animals and humans and lead to a release of a virus from a lab…

Basis for Assessment that Research-Related Incident is More Likely Origin of SARS-CoV-2

Nearly three years after the COVID-19 pandemic began, substantial evidence demonstrating that the **COVID-19 pandemic was the result of a research-related incident** has emerged. A research-related incident is consistent with the early epidemiology showing rapid spread of the virus in Wuhan, with the earliest calls for assistance being located in the near the WIV's original campus in central Wuhan. It also explains the low genetic diversity of the earliest known SARS-CoV-2 human infections in Wuhan, because the likely index case, would be an infected researcher, is the likely primary source of the virus in Wuhan. A research-related incident also explains the failure to find an intermediate host as well as the failure to find any animal infections pre-dating human COVID-19 cases."

[1086] **ADDED since 2/8/2022**

The French Connection: Moderna CEO Stéphane Bancel, the Wuhan Lab, and a curious gene patent

Courageous Discourse
John Leake
October 28, 2022
https://petermcculloughmd.substack.com/p/the-french-connection

"On February 21, 2022, *Frontiers in Virology* published a report titled MSH3 Homology and Potential Recombination Link to SARS-CoV-2 Furin Cleavage Site. The Furin Cleavage Site is the component of the SARS-CoV-2 spike protein that enables the virus to dock onto human lung epithelial cells, thereby initiating the viral replication process. It is the key feature of SARS-CoV-2 that made it infectious to humans. Examining the genetic code of this part of the spike protein, the authors noted that part of the sequence was a **perfect match to a genetic sequence patented in 2016** by Bancel S. et al. in Cambridge, Massachusetts.

> *SARS-CoV-2 Spike Protein and MSH3*
>
> *A peculiar feature of the nucleotide sequence encoding the PRRA furin cleavage site in the SARS-CoV-2 S protein is its two consecutive CGG codons. This arginine codon is rare in coronaviruses: relative synonymous codon usage (RSCU) of CGG in pangolin CoV is 0, in bat CoV 0.08, in SARS-CoV 0.19, in MERS-CoV 0.25, and in SARS-CoV-2 0.299 (8).*
>
> *A BLAST search for the 12-nucleotide insertion led us to a 100% reverse match in a proprietary sequence (SEQ ID11652, nt 2751-2733) found in the US patent 9,587,003 filed on Feb. 4, 2016 (9)*

On the question of whether this perfect match could be merely coincidental, the authors noted:

> Conventional biostatistical analysis indicates that the **probability** of this sequence randomly being present in a 30,000-nucleotide viral genome is **3.21×10^-11**."

Full text:

MSH3 Homology and Potential Recombination Link to SARS-CoV-2 Furin Cleavage Site
Frontiers in Virology
Balamurali K. Ambati, Akhil Varshney, *et al*.
February 21, 2022
https://www.frontiersin.org/articles/10.3389/fviro.2022.834808/full

[1087] **ADDED since 2/8/2022**

Endonuclease fingerprint indicates a synthetic origin of SARS-CoV-2
Valentin Bruttel (University Clinics of Würzburg, Germany), Alex Washburne (Selva Analytics), and Antonius Van Dongen (Duke University)
October 20, 2022
https://www.biorxiv.org/content/10.1101/2022.10.18.512756v1.full.pdf

"**Lay Summary**: To construct synthetic variants of natural coronaviruses in the lab, researchers often use a method called in vitro genome assembly. This method utilizes special enzymes called restriction enzymes to generate DNA building blocks that then can be "stitched" together in the correct order of the viral genome. To make a virus in the lab, researchers usually engineer the viral genome to add and remove stitching sites, called restriction sites. The ways researchers modify these sites can serve as fingerprints of in vitro genome assembly.

We found that SARS-CoV has the restriction site fingerprint that is typical for syntheticviruses. The synthetic fingerprint of SARS-CoV-2 is anomalous in wild coronaviruses, and common in lab-assembled viruses. The type of mutations (synonymous or silent mutations) that differentiate the restriction sites in SARS-CoV-2 are characteristic of engineering, and the concentration of these silent mutations in the restriction sites is extremely unlikely to have arisen by random evolution. Both the restriction site fingerprint and the pattern of mutations generating them are **extremely unlikely in wild coronaviruses** and **nearly universal in synthetic viruses**. Our findings strongly suggest a synthetic origin of SARS-CoV2."

[1088] **ADDED since 2/8/2022**

The Lancet Commission on lessons for the future from the COVID-19 pandemic
The Lancet
Jeffrey D. Sachs, Salim S. Abdool Karim, *et al*.
September 14, 2022
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01585-9/fulltext

"**The origins of SARS-CoV-2**…

As of the time of publication of this report, **all three research-associated hypotheses are still plausible**: infection in the field, infection with a natural virus in the laboratory, and infection with a manipulated virus in the laboratory. No independent, transparent, and science-based investigation has been carried out regarding the bioengineering of SARS-like viruses that was underway before the outbreak of COVID-19. The laboratory notebooks, databases, email records, and samples of institutions involved in such research have not been made available to independent researchers. Independent researchers have not yet investigated the US laboratories engaged in the laboratory manipulation of SARS-CoV-like viruses, nor have

they investigated the details of the laboratory research that had been underway in Wuhan. Moreover, **the US National Institutes of Health (NIH) has resisted disclosing details of the research on SARS-CoV-related viruses that it had been supporting**, providing extensively redacted information only as required by Freedom of Information Act lawsuits."

[1089] **ADDED since 2/8/2022**

Video (2m): *Jeffrey Sachs on COVID – "I'm pretty convinced it came out of US lab biotechnology*
Remarks by Jeffrey Sachs at the GATE Center in Spain
June 2022
https://www.youtube.com/watch?v=HbaZnSBBBVc

Sachs: "I'll add one provocative statement… I chaired the commission for The Lancet for two years on COVID. I'm pretty convinced **it came out of US lab biotechnology**, not out of nature. Just to mention, after two years of intensive work on this. So it's a blunder, in my view, of biotech, not an accident of a natural spillover. We don't know for sure, I should be absolutely clear. But there is enough evidence that it should be looked into, and it's not being investigated, not in the United States, not anywhere. And I think for real reasons that they don't want to look underneath the rug too much."

[1090] **ADDED since 2/8/2022**

A call for an independent inquiry into the origin of the SARS-CoV-2 virus
Proceedings of the National Academy of Sciences of the United States of America
Neil L. Harrison and Jeffrey D. Sachs
May 19, 2022
https://www.pnas.org/doi/10.1073/pnas.2202769119

"The investigation into the origin of the virus has been made difficult by the lack of key evidence from the earliest days of the outbreak—there's no doubt that greater transparency on the part of Chinese authorities would be enormously helpful. Nevertheless, we argue here that there is much important information that can be gleaned from **US-based research institutions**, information not yet made available for independent, transparent, and scientific scrutiny.

The data available within the United States would explicitly include, but are not limited to, viral sequences gathered and held as part of the PREDICT project and other funded programs, as well as sequencing data and laboratory notebooks from US laboratories. We call on US government scientific agencies, most notably the NIH, to support a full, independent, and transparent investigation of the origins of SARS-CoV-2. This should take place, for example, within a tightly focused science-based bipartisan Congressional inquiry with full investigative powers, which would be able to ask important questions—but avoid misguided witch-hunts governed more by politics than by science…

We do not assert that laboratory manipulation was involved in the emergence of SARS-CoV-2, although it is apparent that it could have been. However, we do assert that there has been no independent and transparent scientific scrutiny to date of the full scope of the US-based evidence.

The relevant US-based evidence would include the following information: laboratory notebooks, virus databases, electronic media (emails, other communications), biological

samples, viral sequences gathered and held as part of the PREDICT project (7) and other funded programs, and interviews of the EHA-led research team by independent researchers, together with a full record of US agency involvement in funding the research on SARS-like viruses, especially with regard to projects in collaboration with Wuhan-based institutions."

[1091] **ADDED since 2/8/2022**

Open Letter to the Honorable Xavier Becerra, Secretary of US Department of Health and Human Services

The Committee on Oversight and Reform & the Committee of the Judiciary, US House of Representatives
January 11, 2022
https://republicans-oversight.house.gov/wp-content/uploads/2022/01/Letter-Re.-Feb-1-Emails-011122.pdf

"We write to request a transcribed interview of Dr. Anthony Fauci, Director, U.S. National Institute of Allergy and Infectious Diseases (NIAID). Excerpts of emails we are making public today (see enclosed Appendix I) reveal that **Dr. Fauci was warned of two things**: (1) the potential that COVID-19 leaked from the Wuhan Institute Virology (WIV) and (2) the possibility that the virus was intentionally genetically manipulated. It is imperative we investigate if this information was conveyed to the rest of the government and whether this information would have changed the U.S. response to the pandemic…

Rather than be transparent with the Committee, HHS and NIH continue to hide, obfuscate, and shield the truth. By continuing to refuse to cooperate with our request, your agencies are choosing to hide information that will help inform the origins of the ongoing pandemic, prevent future pandemics, respond to future pandemics, inform the United States' current national security posture, and restore confidence in our public health experts. HHS and NIH's continued obstruction is likely to cause irreparable harm to the credibility of these agencies. The emails released today raise significant questions, including but not limited to:

1. Did Drs. Fauci or Collins warn anyone at the White House about the potential COVID-19 originated in a lab and could be intentionally genetically manipulated?

2. If these concerns were not shared, why was the decision to keep them quiet made?

3. What new evidence, if any, came to light about COVID-19 between February 1, 2020 and February 4, 2020 to alter the belief it originated in a lab?

4. Did Drs. Fauci or Collins edit the Nature Medicine paper entitled 'The Proximal Origin of SARS-CoV-2'"

[1092] **ADDED since 2/8/2022**

NIH Documents Provide New Evidence U.S. Funded Gain-of-Function Research in Wuhan

The Intercept
Sharon Lerner, Mara Hvistendahl, Maia Hibbett
September 9, 2021
https://theintercept.com/2021/09/09/covid-origins-gain-of-function-research/

"Documents obtained by *The Intercept* contain new evidence that the Wuhan Institute of Virology and the nearby Wuhan University Center for Animal Experiment, along with their collaborator, the U.S.-based nonprofit EcoHealth Alliance, have engaged in what the U.S.

government defines as 'gain-of-function research of concern,' intentionally making viruses more pathogenic or transmissible in order to study them, despite stipulations from a U.S. funding agency that the money not be used for that purpose.

Grant money for the controversial experiment came from the National Institutes of Health's National Institute of Allergy and Infectious Diseases, which is headed by Anthony Fauci. The award to EcoHealth Alliance, a research organization which studies the spread of viruses from animals to humans, included subawards to Wuhan Institute of Virology and East China Normal University. The principal investigator on the grant is EcoHealth Alliance President Peter Daszak, who has been a key voice in the search for Covid-19's origins."

[1093] **ADDED since 2/8/2022**

Inside the risky bat-virus engineering that links America to Wuhan
MIT Technology Review
Rowan Jacobsen
June 29, 2021
https://www.technologyreview.com/2021/06/29/1027290/gain-of-function-risky-bat-virus-engineering-links-america-to-wuhan/

"In 2013, the American virologist Ralph Baric approached Zhengli Shi at a meeting. Baric was a top expert in coronaviruses, with hundreds of papers to his credit, and Shi, along with her team at the Wuhan Institute of Virology, had been discovering them by the fistful in bat caves. In one sample of bat guano, Shi had detected the genome of a new virus, called SHC014, that was one of the two closest relatives to the original SARS virus, but her team had not been able to culture it in the lab.

Baric had developed a way around that problem—a technique for "reverse genetics" in coronaviruses. Not only did it allow him to bring an actual virus to life from its genetic code, but he could mix and match parts of multiple viruses. He wanted to take the "spike" gene from SHC014 and move it into a genetic copy of the SARS virus he already had in his lab. The spike molecule is what lets a coronavirus open a cell and get inside it. The resulting chimera would demonstrate whether the spike of SHC014 would attach to human cells..."

[1094] **ADDED since 2/8/2022**

Video (10m): *Ex-CDC boss believes Covid-19 virus came from China lab*
CNN interview with Dr. Robert Redfield, former Director of the Centers for Disease Control (CDC)
March 26, 2021
https://www.youtube.com/watch?v=f0_RhfT21bw

Redfield: "If I was to guess, this virus started transmitting somewhere in September or October in Wuhan…

I am of the point of view that I still think the most likely etiology of this pathogen in Wuhan was from a **laboratory**, you know, escaped…

It's not unusual for respiratory pathogens that are being worked on in a laboratory to infect a laboratory worker."

[1095] ***COVID-19, SARS and Bats Coronaviruses Genomes Peculiar Homologous RNA Sequences***
International Journal of Research
Jean Claude Perez and Luc Montagnier
July 30, 2020
https://www.granthaalayahpublication.org/journals/index.php/granthaalayah/article/view/IJRG20_B07_3568/691

"**Abstract**: … This article shows how 16 fragments (Env Pol and Integrase genes) from different strains, both diversified and very recent, of the HIV1, HIV2 and SIV retroviruses have high percentage of homology into parts of the genome of COVID_19. Moreover each of these elements is made of 18 or more nucleotides and therefore may have a function. They are called Exogenous Informative Elements (EIE)…

Here are the two main facts which contribute to **our hypothesis of a partially synthetic genome**: … [*emphasis added*]

In the comparative analysis of both SPIKES genes of COVID_19 and Bat RaTG13 we note two abnormal facts:

1) the insertion of 4 contiguous PRRA amino acids in the middle of SPIKE (we show that this site was already an optimal cleavage site BEFORE this insertion).

2) an abnormal distribution of synonymous codons in the second half of SPIKE.

Finally we show the insertion in this 1770 bases SPIKE region of a significant pair of EIEs from Plasmodium Yoelii and of apossible HIV1 EIE with a crucial Spike mutation."

[1096] ***The Evidence which Suggests that This Is No Naturally Evolved Virus - A Reconstructed Historical Aetiology of the SARS-CoV-2 Spike***
University of London
Birger Sørensen, Angus Dalgleish, and Andres Susrud
July 1, 2020
https://21a86421-c3e0-461b-83c2-cfe4628dfadc.filesusr.com/ugd/659775_31f83ded084b4b01a97963630dc2ae1d.pdf

"**Abstract**: To discover exactly how to attack SARS-CoV-2 safely and efficiently, our vaccine candidate Biovacc-19 was designed by first carefully analysing the biochemistry of the Spike. We ascertained that it is highly unusual in several respects, unlike any other CoV in its clade. The SARS-CoV-2 general mode of action is as a co-receptor dependent phagocyte. But data shows that simultaneously it is capable of binding to ACE2 receptors in its receptor binding domain. In short, SARS-CoV-2 is possessed of dual action capability. In this paper we argue that **the likelihood of this being the result of natural processes is very small** [*emphasis added*]. The spike has six inserts which are unique fingerprints with five salient features indicative of purposive manipulation. We then add to the bio-chemistry a diachronic dimension by analysing a sequence of four linked published research projects which, we suggest, show by deduction how, where, when and by whom the SARS-CoV-2 Spike acquired its special characteristics. This reconstructed historical aetiology meets the criteria of means, timing, agent and place to produce sufficient confidence to reverse the burden of proof. Henceforth, those who would maintain that the Covid-19 pandemic arose from zoonotic transfer need to

explain precisely why this more parsimonious account is wrong before asserting that their evidence is persuasive, most especially when, as we also show, there are puzzling errors in their use of evidence."

[1097] **ADDED since 2/8/2022**

Video (2m): *Anthony Fauci predicts pandemic — 2017 Georgetown Keynote Address*
2017
https://rumble.com/vp8k7c-anthony-fauci-predicts-pandemic-2017-georgetown-keynote-address.html

"If there's one message that I want to leave with you today based on my experience… is that there is no question that there will be a challenge to the coming administration in the arena of infectious diseases, both chronic infectious diseases… but also there will be a surpsise outbreak."

[1098] **ADDED since 2/8/2022**

A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence
Nature Medicine — University of North Carolina at Chapel Hill
Vineet D. Menachery, Boyd L. Yount, Jr., Ralph S. Baric, *et al*.
November 9, 2015
https://www.nature.com/articles/nm.3985

"**Biosafety and biosecurity**: Reported studies were initiated after the University of North Carolina Institutional Biosafety Committee approved the experimental protocol (Project Title: Generating infectious clones of bat SARS-like CoVs; Lab Safety Plan ID: 20145741; Schedule G ID: 12279). **These studies were initiated before** the US Government Deliberative Process Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS and SARS Viruses (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf). This paper has been reviewed by the funding agency, the NIH. Continuation of these studies was requested, and **this has been approved by the NIH**."

[1099] **ADDED since 2/8/2022**

Project Grant; FAIN R01AI110964
June 1, 2014
https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529

"**Awarding Agency**: Department of Health and Human Services (HHS)

Recipient: ECOHEALTH ALLIANCE INC.

Assistance Listings (CFDA Programs): 98.855 – ALLERGY AND INFECTIOUS DISEASES RESEARCH

Start Date: Jun 01, 2014

End Date: Dec 31, 2026

$ Award Amounts: $3.7 Million

Description: UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE

Isolation of COVID-19

[1100] ***CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel***
Centers for Disease Control and Prevention (CDC)
Effective July 21, 2021
https://www.fda.gov/media/134922/download

> "The analytical sensitivity of the rRT-PCR assays contained in the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel were determined in Limit of Detection studies. Since **no quantified virus isolates of the 2019-nCoV were available for CDC use at the time the test was developed** and this study conducted, assays designed for detection of the 2019-nCoV RNA were tested with characterized stocks of in vitro transcribed full length RNA (N gene; GenBank accession: MN908947.2) of known titer (RNA copies/µL) spiked into a diluent consisting of a suspension of human A549 cells and viral transport medium (VTM) to **mimic clinical specimen** *[emphasis added]*."

[1101] **ADDED since 2/8/2020**
Video (3m): *Return to Wuhan: What Life Is Like One Year Later*
NBC News interview with Dr. Wu Zunyou, Chief Epidemiologist for the Chinese Centre for Disease Control
NBC News
January 24, 2021
https://www.youtube.com/watch?v=YbSdG2imqEM

> **NBC journalist**: "It still isn't clear if the Huanan market was the source of the virus, though outside experts believe it was a starting point for the outbreak."
>
> **NBC journalist**: "Where Chinese officials took samples over a year ago."
>
> **Interview with Zunyou (1:57):**
>
> > **Interviewer**: "Why has the data not been shared?"
> >
> > **Zunyou**: "**They didn't isolate the virus**. That's the issue."

Evidence of Planning for Vaccine Passports

[1102] ***Roadmap for the Implementation of Actions by the European Commission based on the Commission Communication and the Council Recommendation on Strengthening Cooperation against Vaccine Preventable Diseases***
European Commission
Last update: Q3 2019
https://ec.europa.eu/health/sites/default/files/vaccination/docs/2019-2022_roadmap_en.pdf

"**Action**: Examine the feasibility of developing a common vaccination card/passport for EU citizens (that takes into account potentially different national vaccination schedules and), that is compatible with electronic immunisation information systems and recognized for use across borders, without duplicating work at national level.

Timelines and Deliverables:

- 2019-2021 – Feasibility study for the development of a common EU vaccination card
- 2022 – Commission proposal for a common vaccination card/passport for EU citizens…

Action: Develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems… "

5G & Wireless Communications Radiation

[1103] ***Evidence for a connection between coronavirus disease-19 and exposure to radiofrequency radiation from wireless communications including 5G***
Journal of Clinical and Translational Research
Beverly Rubik and Robert R. Brown
September 29, 2021
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8580522/

"**Background and Aim**: Coronavirus disease (COVID-19) public health policy has focused on the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus and its effects on human health while environmental factors have been largely ignored. In considering the epidemiological triad (agent-host-environment) applicable to all disease, we investigated a possible environmental factor in the COVID-19 pandemic: ambient radiofrequency radiation from wireless communication systems including microwaves and millimeter waves. SARS-CoV-2, the virus that caused the COVID-19 pandemic, surfaced in Wuhan, China shortly after the implementation of city-wide (fifth generation [5G] of wireless communications radiation [WCR]), and rapidly spread globally, initially demonstrating a statistical correlation to international communities with recently established 5G networks. In this study, we examined the peer-reviewed scientific literature on the detrimental bioeffects of WCR and identified several mechanisms by which **WCR may have contributed to the COVID-19 pandemic as a toxic environmental cofactor** [*emphasis added*]. By crossing boundaries between the disciplines of biophysics and pathophysiology, we present evidence that WCR may: (1) cause morphologic changes in erythrocytes including echinocyte and rouleaux formation that can contribute to hypercoagulation; (2) impair microcirculation and reduce erythrocyte and hemoglobin levels exacerbating hypoxia; (3) amplify immune system dysfunction, including immunosuppression, autoimmunity, and hyperinflammation; (4) increase cellular oxidative stress and the production of free radicals resulting in vascular injury and organ damage; (5) increase intracellular Ca2+ essential for viral entry, replication, and release, in addition to promoting pro-inflammatory pathways; and (6) worsen heart arrhythmias and cardiac disorders.

Relevance for Patients: In short, WCR has become a ubiquitous environmental stressor that we propose may have contributed to adverse health outcomes of patients infected with SARS-CoV-2 and increased the severity of the COVID-19 pandemic. Therefore, we recommend that all people, particularly those suffering from SARS-CoV-2 infection, reduce their exposure to WCR as much as reasonably achievable until further research better clarifies the systemic health effects associated with chronic WCR exposure."

Censorship and ‘Fact Checking’

Note: The citations below are presented in reverse, chronological order.

[1104] **ADDED since 2/8/2022**

The Twitter Files: How Twitter Rigged the COVID Debate
David Zweig
December 26, 2022
https://www.thefp.com/p/how-twitter-rigged-the-covid-debate

> “I had always thought a primary job of the press was to be skeptical of power—especially the power of the government. But during the Covid-19 pandemic, I and so many others found that the legacy media had shown itself to largely operate as a messaging platform for our public health institutions. Those institutions operated in near total lockstep, in part by purging internal dissidents and discrediting outside experts…
>
> The United States government pressured Twitter to elevate certain content and suppress other content about Covid-19 and the pandemic. Internal emails that I viewed at Twitter showed that both the Trump and Biden administrations directly pressed Twitter executives to moderate the platform’s content according to their wishes…
>
> And it wasn’t just Twitter. The meetings with the Trump White House were also attended by Google, Facebook, Microsoft and others.
>
> When the Biden administration took over, its agenda for the American people can be summed up as: Be very afraid of Covid and do exactly what we say to stay safe…
>
> Throughout the pandemic, Twitter repeatedly propped up the official government line that prioritizing mitigation over other concerns was the best approach to the pandemic. Information that challenged that view—for example, that pointed out the low risk children faced from the virus, or that raised questions about vaccine safety or effectiveness—was subject to moderation and suppression.”

[1105] **ADDED since 2/8/2022**

California: Docs may be disciplined for spreading COVID lies
AP News
September 30, 2022
https://apnews.com/article/health-business-california-covid-gavin-newsom-95397f4783a19b6fb35d2c46ac6f872e

> **Note**: For the text of this bill, see [1106].
>
> “Doctors who spread coronavirus lies could be disciplined for unprofessional conduct in California under a law signed Friday by Gov. Gavin Newsom.
>
> The bill, AB2098, introduced by Democratic Assembly Member Evan Low, declares that a physician or surgeon commits professional misconduct if they disseminate “misinformation or disinformation” about the nature and risks of COVID-19, its prevention and treatment and the development, safety and effectiveness of vaccines.

A doctor who commits such conduct could face discipline by the state medical board or osteopathic medical board and in severe cases, could potentially **lose their license** to practice in California."

[1106] **ADDED since 2/8/2022**

California Assembly Bill 2098 — Physicians and surgeons: unprofessional conduct
California State Legislature
Coauthors: Assembly Members Aguiar-Curry, Akilah Weber, and Wicks; Senators Pan and Wiener
February 14, 2022
https://legiscan.com/CA/text/AB2098/id/2604233

"Existing law provides for the licensure and regulation of physicians and surgeons by the Medical Board of California and the Osteopathic Medical Board of California. Existing law requires the applicable board to take action against any licensed physician and surgeon who is charged with unprofessional conduct, as provided.

This bill would designate the dissemination of misinformation or disinformation related to the SARS-CoV-2 coronavirus, or "COVID-19," as unprofessional conduct. The bill would also make findings and declarations in this regard."

[1107] ***Rapid Response: Open letter from The BMJ to Mark Zuckerberg***
British Medical Journal
Fiona Godlee and Kamran Abbasi
December 17, 2021
https://www.bmj.com/content/375/bmj.n2635/rr-80

"We are Fiona Godlee and Kamran Abbasi, editors of The BMJ, one of the world's oldest and most influential general medical journals. We are writing to raise **serious concerns about the 'fact checking' being undertaken by third party providers on behalf of Facebook/Meta** [*emphasis added*].

In September, a former employee of Ventavia, a contract research company helping carry out the main Pfizer covid-19 vaccine trial, began providing The BMJ with dozens of internal company documents, photos, audio recordings, and emails. These materials revealed a host of poor clinical trial research practices occurring at Ventavia that could impact data integrity and patient safety. We also discovered that, despite receiving a direct complaint about these problems over a year ago, the FDA did not inspect Ventavia's trial sites.

The BMJ commissioned an investigative reporter to write up the story for our journal. The article was published on 2 November, following legal review, external peer review and subject to The BMJ's usual high level editorial oversight and review.

But from November 10, readers began reporting a variety of problems when trying to share our article. Some reported being unable to share it. Many others reported having their posts flagged with a warning about 'Missing context ... Independent fact-checkers say this information could mislead people'…

We find the "fact check" performed by Lead Stories to be inaccurate, incompetent and irresponsible.

It fails to provide any assertions of fact that The BMJ article got wrong…

There is also a wider concern that we wish to raise. We are aware that **The BMJ is not the only high quality information provider to have been affected by the incompetence of Meta's fact checking regime** [*emphasis added*]… Rather than investing a proportion of Meta's substantial profits to help ensure the accuracy of medical information shared through social media, you have apparently delegated responsibility to people incompetent in carrying out this crucial task. Fact checking has been a staple of good journalism for decades. What has happened in this instance should be of concern to anyone who values and relies on sources such as The BMJ."

[1108] **Motion to Dismiss Complaint: *John Stossel, an individual, Plaintiff v. Facebook, Inc., a Delaware corporation; Science Feedback, a French non-profit organization; and Climate Feedback, a French non-profit organization***
United States District Court, Northern District of California, San Jose Division
Filed November 29, 2021
https://wattsupwiththat.com/wp-content/uploads/2021/12/Facebook-admits-its-fact-check-is-opinion-page-2.pdf

"Stossel's claims focus on the fact-check articles written by Climate Feedback, not the labels affixed through the Facebook platform. The labels themselves are neither false nor defamatory; to the contrary, they constitute **protected opinion** [*emphasis added*]. And even if Stossel could attribute Climate Feedback's separate webpages to Meta, the challenged statements on those pages are likewise neither false nor defamatory."

[1109] **Complaint for Defamation: *John Stossel, an individual, Plaintiff v. Facebook, Inc., a Delaware corporation; Science Feedback, a French non-profit organization; and Climate Feedback, a French non-profit organization***
United States District Court, Northern District of California, San Jose Division
Filed September 22, 2021
https://s3.documentcloud.org/documents/21068069/stossel.pdf

"Facebook placed a label prominently over or below the Fire Video, stating 'Missing Context. Independent fact-checkers say this information could mislead people,' under which was a button stating 'See Why'…

Defendants flagged Stossel's reporting as failing a 'fact-check' and being 'misleading' and 'missing context,' based on their false attribution to Stossel of the 'climate change doesn't cause forest fires' claim that he never made…

As the foregoing facts confirm, Defendants' 'fact-check' process is nothing more than a pretext used by Defendants to defame users with impunity, particularly when Defendants disagree with the scientific opinions expressed in user content. Often, the pretext appears to be invoked based on implicit or explicit viewpoint biases…

The False Statements tend directly to injure Stossel in his profession and occupation, and exposed him to hatred, contempt, ridicule, and/or shame, and discouraged others from associating or dealing with him. The False Statements, by natural consequence, caused actual damage to Stossel, in the form of reduced distribution of his reporting, reduced viewership, and reduced profits from advertising revenue from viewership. In addition, the False Statements have caused Stossel irreparable reputational harm, which is ongoing…

It further alleges, "Defendants acted with malice when they published the False Statements. Defendants knew, or should have known, that Stossel's reporting contained no false facts – only scientific opinions with which Defendants disagreed – yet Defendants publicly declared that the Alarmism Video had failed a 'fact-check,' contained 'factual inaccuracies,' and was 'partly false.' Further, Defendants continued to publish their False Statements after Stossel repeatedly put Defendants on notice of their falsity."

Resources for Personal Use

[1110] ***Covid-19 Resources: Medical, Legal, Forms, Jobs & Other Critical Information***
September 15, 2021
https://www.coreysdigs.com/health-science/covid-19-resources-medical-legal-forms-jobs-other-critical-information/

[1111] ***Resources***
Doctors for COVID Ethics
https://doctors4covidethics.org/resources-2/

[1112] ***Form for Employees Whose Employers Are Requiring Covid-19 Injections***
https://pandemic.solari.com/wp-content/uploads/2021/05/Form_Employees_Whose_Employers_Are_Requiring_Covid-19_Injections.pdf

[1113] ***How Americans can resist coronavirus shot mandates – a comprehensive guide***
September 10, 2021
https://www.lifesitenews.com/news/resources-for-americans-pushing-back-against-mandated-coronavirus-vaccines/

[1114] **ADDED since 2/8/2022**
React19
https://react19.org/

"React19 is a science-based non-profit offering financial, physical, and emotional support for those suffering from long-term COVID-19 vaccine adverse events globally. Our mission is to bring healing to the moms, dads, friends, and loved ones who are facing life-altering side effects from their COVID-19 vaccine. We build bridges between patients and research institutions in order to develop a better understanding of our vaccine complications."

[1115] **ADDED since 2/8/2022**

#CanWeTalkAboutIt

https://www.canwetalkaboutit.org/

"**Our Mission**: The #CanWeTalkAboutIt campaign aims to start the conversation and break the silence about COVID-19 vaccine injury and death. We want to raise awareness, create a safe space for the injured to tell their stories and raise funds to support global projects. The funding will support organizations and initiatives globally that are working on health solutions, research, and lawful processes leading to compensation for the injured.

Our main objectives are to:

- Create a safe space for the vaccine injured to speak out
- Raise awareness about the problem with vaccine injuries
- Raise funds for health solutions, research and lawful processes

We want to give the vaccine injured their dignity and their lives back."

[1116] **MyFreeDoctor.com**

Endorsed by the Association of American Physicians and Surgeons (AAPS)

https://myfreedoctor.com/

"We are a free, donation supported, medical consultation service that connects patients directly to a doctor. At this time, we are primarily focused on the treatment of Covid-19."

[1117] **Form: *Directive to Physicians and Family or Surrogates Regarding COVID19 or Variants thereof and Treatment Protocols***

Dr. Bryan Ardis

https://thedrardisshow.com/medical-directive-to-physician

"**Directive**: I, _____, recognize that the best health care is based upon a partnership of trust and communication with my physician. My physician and I will make health care or treatment decisions together as long as I am of sound mind and able to make my wishes known. If there comes a time that I am unable to make medical decisions about myself because of illness or injury, I direct that the following treatment preferences be honored: …"

Organizations

[1118] **America's Frontline Doctors**
https://americasfrontlinedoctors.org/

[1119] **Association of American Physicians and Surgeons**
https://aapsonline.org/

[1120] **Brownstone Institute**
https://brownstone.org/

[1121] **Canadian Covid Care Alliance**
https://www.canadiancovidcarealliance.org/

[1122] **Children's Health Defense**
https://childrenshealthdefense.org/

[1123] **Doctors for COVID Ethics**
https://doctors4covidethics.org/

[1124] **Front Line COVID-19 Critical Care Alliance**
https://covid19criticalcare.com/

[1125] **Global Covid Summit**
https://globalcovidsummit.org/

[1126] **Great Barrington Declaration**
https://gbdeclaration.org/

[1127] **GreenMedInfo**
https://www.greenmedinfo.com/

[1128] **Informed Consent Action Network**
https://www.icandecide.org/

[1129] **National Health Federation**
https://thenhf.com/

[1130] **Stop World Control**
https://www.stopworldcontrol.com/

[1131] **Truth for Health Foundation**
https://www.truthforhealth.org/

[1132] **The Control Group**
https://www.vaxcontrolgroup.com/

[1133] **The Unity Project**
https://unityprojectonline.com/